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A STUDY ON VIRANA SILETHUMAM (DISSERTATION SUBJECT)



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1. INTRODUCTION

Siddha system of medicine has virtually classified diseases into 4448 types on basis of the three humours ie, Vatham, Pitham, Kabam constituting the fundamentals of this system. According to Classical Siddha literatures derangement of kabam can lead to 21 different types of illnesses, of which Virana Silethumam is one of the disease.

The clinical picture of virana silethumam includes sore throat with mucous and pustular exudates, swelling of anterior and posterior cervical area with fever, rigor, burning sensation all over the body, cough, crying out of severity, ulceration of throat and tongue. The symptomatology of Virana silethumam may be comparable with that of Acute Pharyngo-tonsillitis.

Around the world sore throat is one of the very common recurrent illnesses in children of which 37% being diagnosed as acute bacterial Pharyngo-tonsillitis¹. It is a common condition nearly all children are becoming infected atleast once. Indian children are more prone to the risk of developing complications like rheumatic fever, acute glomerulonephritis due to the prevailing unhygienic conditions. About 80% of children with obstructive sleep apnoea are suffering from tonsillar hypertrophy².

The initial management for infected tonsils in allopathic medicine is antibiotics. If frequent infections or trouble breathing occur tonsillectomy will be done. Administration of antibiotics and analgesics to children have resulted in the development of higher resistance recurrences, Reye's syndrome, etc (*Arora et al, 1999*) and also kill healthy intestinal bacteria which helps to keep the immune system healthy.

Around 200,000 tonsillectomies are done annually in India which is the commonest surgical procedure in children. Tonsillectomy also has demerits children like post-operative haemorrhage, pain, nausea, vomiting etc..

This compels me to explore an efficacious anti-microbial drug which is purely herbal, adequately safe and easily available for pediatric population. The constituents of trial drug *Coriandrum sativum*, *Cuminum cyminum*, *Nigella sativa* possess antibacterial activity. *Glycyrrhiza glabra* possess anti-inflammatory and anti-allergic activity. Also the drug has essential oil containing predominantly derivative of Eugenol(*Hattori et al 1986*), which act potently against 25 genera of bacteria (including *Streptococcus*, *B.subtilis*), some of which are involved in causing pharyngo tonsillitis (*Ghelardini et al 2007*).

In our research, we have studied the clinical efficacy of the experimental formulation in children. The above said formulation ingredients are herbal origin only. Even though the drugs are pure herb, we have studied preclinical safety study. It shows that the formulation has potential anti-inflammatory activity clinically effective in the management of Virana Silethumam.

2. AIM & OBJECTIVES

AIM

- To study the efficacy of Malli chooranam for the management of Virana silethumam with reduction of clinical symptoms.
- To ensure a combined approach of modern and siddha concepts for the clinical diagnosis of the Virana silethumam.

OBJECTIVES

- To evaluate the Safety of *Malli Chooranam* by Acute and Sub acute Toxicity studies in animal models.
- To evaluate the Safety and Efficacy of *Malli Chooranam* in pediatric population..
- To study the subjective changes of
 - Udal kattugal,
 - Ennvagai Thervu and
 - Mukkutram in patients with Virana silethumam.
- To elucidate the correlative aspects of Virana silethumam and Acute Pharyngo-tonsillitis in terms of clinical manifestations.

3. REVIEW OF LITERATURE

SIDDHA ASPECTS

The term Virana silethumam, etiology and clinical manifestations is briefed in *Siddha maruthuvam- Pothu* text. Information regarding various features was collected from other Siddha literatures.

இயல் (DEFINITION) :

Accumulation of phlegm in the throat, chest leads to derangement of kabam, pitham in areas of throat, nose, tonsil producing inflammation and exudation of mucus, phlegmatic secretions from these regions.

வேறு பெயர்கள் (SYNONYMS):

தொண்டைக்குரு	-Thondai Kuru ³
தொண்டைக்கட்டு	-Thondai Kattu ⁵
தொண்டை கபம்	-Thondai Kabam ⁵
தொண்டைக் கிரந்தி வீக்கம்	-Thondai Kirandhi veekam ⁴
தொண்டையில் வளரும் சதை	-Thondail Valarum sathai ⁶
குரற்கம்மல்	-Kural Kammal ⁵
கள பிருந்தம்	-Kala Biruntham ⁵
கள வங்குரம்	-Kala Vanguram ⁵
கள சுண்டி	-Kala Chundi ⁵
கண்டக் கிரந்தி	-Kanda Kiranthi ⁵
கண்ட சந்து ரோகம்	-Kanda Santhu rogam ⁵
கண்ட சாலாகம்	-Kanda Salugam ⁵
கண்ட சுண்டி	-Kanda Sundi ⁵

நோய் வரும் வழி (ETIOLOGY):

Exposure to cold air, excessive eating, frequent intake of sweet and sour taste foods, tubers, previously cooked rice and climatic extremes in the month of masi, panguni will lead to excessive accumulation of Iyam.

According to *Pillai Pini maruthuvam*, accumulation of Kabam in children's throat is caused by

- Poor health condition of mother
- Playing in cold water,
- Frequent eating of cold food items,
- Exposure to cold air,
- Poor nutritional condition of the child.

“சாருமே சிரசில் நின்று தகைத்திடும் குவிடு தொண்டை

வாருமே விலாவு நெஞ்சு மருவிய உறுப்பு தன்னில்

நீருமே உறைந்து கபமும் நின்றது வறட்சியாகி

கூருமே கொடு நீராகி குழந்தைமேல் அடருமென்றே...”

(சிரசிலிருந்து குவிடு, தொண்டை, விலாவு, நெஞ்சு முதலிய உறுப்புகளில் உறைந்த கபம் வறட்சியாகி குழந்தைகள் உடலில் நீராக அடரும்).

In *Kuzhandaigal noigal part-V*, it is said that kabam condensed in areas of head, throat, and chest gets dried further spreading in fluid nature throughout the body

Due to inattentive parental care, concerning actions of child there can be an exacerbation of the phlegm in the chest and others regions.

“சொல்லிய சென்ன கூற்றால் துடர் பழவினையால் வந்து

நல்லவனுறுப்பின் சார்ந்த மருவிய தோஷத்தாலே

அல்லகசிரசில் நீரால் அன்னையின் பாலினாலும்

கல்லக நரம்பில் தாவி கபமது வந்து சாரும்... ”

Previous karmic deeds, thosham of the organs, excessive water in regions of head, ill mother's milk, and affliction of child's nerves leads to accumulation of phlegm in children as told in the above poem taken from *Kuzhandaigal noigal part-V*.

நோய் எண் (CLASSIFICATION):

According to *Siddha Maruthuvam Pothu*, there are 21 types of Silethumam ailments and Virana silethumam is one among them.

முற்றான சிலேட்மந் தானிருபத் தொன்று
முனியுரைத்த சொற்படியே மொழியக் கேளாய்
சிற்றான விருமலாந் சிலேட்மத் தோடு
செறிகாசச் சிலேட்மமாஞ் சுவாசச் சிலேட்மம்
மற்றான தீபனசி லேட்மத் தோடே
மந்தசிலேட் டுமவாத சிலேட்ம மாகும்
துற்றான பித்தசிலேட் மந்தொந்த சிலேட்மஞ்
சுகசன்னி வாதசிலேட் டுமந்தா னாமே.
ஆகுமே சுரசிலேட்ம மதிசார சிலேட்ம
மதிகசல சிலேட்மமா மக்கினி சிலேட்மம்
போகுமே பூதசிலேட்டும் முயலகன்றான்
மொறிவெறிச் சிலேட்மமாம் விகார சிலேட்மம்
சோகுகரோ ணிதசிலேட்மம் **விரண சிலேட்மந்**
துர்கந்த சிலேத்மமா நித்திய சிலேட்மம்
நாகுமே இருபத்தொன் றாஞ்சி லேட்மம்
நாட்டினேன் வரலாறு நயந்து கேளே.
- யூகி சிந்தாமணி

The 21 types of Silethumam are as follows:

1)Irumal 2) Kasam 3) Swasam 4) Theebanam 5) Mantham 6) Vali 7) Azhal 8) Mukkoottu 9) Sugasanni 10) Suram 11) Athisaram 12) Neerkovai 13) Anal 14) Pootham 15) Muyalagan 16) Veri 17) Vigaaram 18) Suronitham 19) **Viranam** 20) Thurkandham 21) Nithtiyam.

முக்குற்ற வேறுபாடுகள் (PATHO-PHYSIOLOGY):

தொண்டையென்பின் சந்தி நிறம் சோற்றுப்பை நாசிதலை
ஒண்டொடியே வமத் துளபித்தத் தொண்ணீர்ச்
சுரப்பி யிரசதாது சுத்த நிணம் நாவும்
தரமான வையத் திடம்.
- மருத்துவ தனி பாடல்

Head, throat, chest, nose, tongue, rasa thathu are main sites of Kapham. It is responsible for the secretory and lubricatory functions of these organs. The chemical changes that takes place alongside; underline the synergy of pitham in maintaining healthy secretory mucosal lining of the sites of kapham. (*Siddha Maruthuva Sudar*)

The etiological factors (“Silettuma malam” in *TV.Sambasivam pillai Dictionary*) cause

1. Derangement of Kapham in first place followed by
2. Derangement of Pitham producing an inflammatory reaction of the lining seretory mucosa.
3. Inorder to excrete the exudative secretions produced, body initiates a sequelae of response leading to morbid condition, Virana Silethumam.

நோய் குறி குணங்கள் (CLINICAL FEATURES):

தானென்ற தொண்டையினிற் புண்ணு மாகிச்

சளியோடு சீத்தாதுங் கலந்து வீழுங்

கானென்ற கழுத்தோடு பிடரிகன்னங்

கனமாக வீங்கியே காய்ச்ச லுண்டாங்

கோனென்ற குளிரோடு எரிவுண் டாகும்

கொக்கென்ற இருமியே கூவ லுண்டாம்

வோனென்ற மிடறெல்லாம் நாவும் புண்ணா

மிக விரண சிலேட்மத்தின் விவரந் தானே.

- யூகி சிந்தாமணி

According to the above poem in *Siddha maruthuvam-pothu*, the clinical manifestations are as follows:

- Ulceration of throat with exudation of mucosal, pustular exudates
- Swelling in neck, nape of neck and cheek accompanied by fever, rigor
- Burning sensation in the body
- Cough, crying out of severity of pain
- Ulcerations of throat and tongue.

Siddha terminologies specifically related to & in support of Virana silethumam was found to be in *Tamil-English Dictionary by TV.Sambasivampillai*. They are,

- Silettuma vali: body ache caused by deranged kapham
- Sileshma thalaivali: A kind of headache in which the palate and the throat secretion to be covered with a coat of sticky mucus with a feeling of cold and heaviness of head, which cannot be turned about.
- Kanda suram: fever caused by deranged kapham.
- Kanda sosham: dryness of throat
- Kanda soolai: pricking pain in throat due to disease of throat glands.
- Kanda peedam: sharp/acute pain in the throat.

பிணி அறிமுறைமை (DIAGNOSIS):

அட்டமாங்கிரி கடன்னை யறிந்து நீயுணரவே
வட்டமாழகங்கள் பல்லுக் வாயதில் நாக்குங்காயங்
கட்டருமலங்கள் கைதனில் நாடிதானுந்
திட்டமாயறிந்து செய்யுந் திறமுள்ள வயித்தியராமே.

(அகத்தியர் ஆயுள் வேதம்-1200).

Since infants and young children may not be correctly able to explain symptoms, diagnosis of diseases depend upon the sharp analytical capability of physician. According to *BalaRoga nithaanam, Kashyaba samhithai*, mild rise in temperature, distaste, excessive salivation, inability to swallow it may be enough in diagnosing a throat disease.

Piniyari muraimai – The method of diagnosing in Siddha is based upon

1. Poriyal arithal (Physician's use of sense organs in examining the affected parts of the patients)
2. Pulanal arithal (Physician's use of the five sense in apprehending the disease).
3. Vinathal (asking informations regarding the history of the disease, its clinical feature etc., from the patient or his close relatives who are taking care of him).
4. Ennvagai thervugal (eight fold examination).

The above principles correspond to the methodology of

(a) Inspection, (b) Palpation and (c) Interrogation as in modern medicine.

In Siddha, among the 10 types of “alavaigal” (analytical tools), first three are very significant and useful in examination of a patient. They are,

1. Kaandal: (Inspection by Siddha method)
2. Karuthal: (Through Siddha Investigations)
3. Urai: (Literature reference of Siddha system)

எண் வகைத் தேர்வு (EIGHT-FOLD EXAMINATION):

"நாடி ஸ்பரிசம் நா நிறம் மொழி விழி

மலம் மூத்திரமிவை மருத்துவ ராயுதம்."

- சித்த மருத்துவ நோய் நாடல் நோய் முதல் நாடல் திரட்டு

"மெய்க்குறி நிறம் தொனி விழி நா இருமலம் கைக்குறி"

- தேரையர்.

This is an important part of diagnosis as framed by siddhars. This includes,

1. ஸ்பரிசம் (Sensation to touch)
2. நா (Tongue)
3. நிறம் (Colour)
4. மொழி (Voice)
5. விழி (Eyes)
6. மலம் (Faeces)
7. மூத்திரம் (Urine)
8. நாடி (Pulse)

1. ஸ்பரிசம் (Sensation to touch):

Sparisam is a method of palpation and percussion to know the condition of the body like warm, fever, chillness, sweating, numbness, paresthesia, dryness of the body, erosion patches, ulcers, edema, emaciation, swelling, obesity and enlargement of liver, spleen.

In Virana silethumam, there is

- Swelling in the cervical region
- Warmth in areas of swelling
- Pain in the areas of swelling
- Fever
- Dryness of skin

2. நா (Tongue) :

This is the method of inspection of the tongue mainly gums, teeth, lips, palate etc. In Virana silethumam,

- Whitish nature of the tongue with coating and pallor was observed indicating the derangement of Silethumam.
- Soreness at the edges of the tongue during fever indicating aggravation of pitham.

3. நிறம் (Colour) :

Colour (indicating the vatham, pitham, kabam, mukkutram) yellow, pallor, redness of the skin and colour of nail beds are noted. In Virana silethumam, pallor of skin will be present as it is one of the kabam ailments.

4. மொழி (Voice):

Clarity of voice, any disturbances in speech, loud voice, slurring, crying, talk induced by hallucination are noted. In Virana silethumam, voice disturbances are due to sore throat and hoarseness of voice. Difficulty in speaking is due to excessive pain in swallowing the saliva.

5. விழி (Eyes) :

Abnormal colour changes indicate the three thodams. Pallor, excessive lacrimation, accumulation of secretion at the angle of eyes, subconjunctival bleeding, and any specific diseases in the eyes are noted. In Virana silethumam, pallor of conjunctivae is present. In few, there is diffuse congestion of the conjunctivae due to continuous cough.

6. மலம் (Faeces) :

மலமுத்திரக்குறி செப்பிடிந் மலைமேற்பகுதி விளக்காம்
மையற்கொடு கணையாகிய மௌவந் திணையாமே
மலமானது புயலாமென்றிற் மன்னிற் பெறுசுரமே
மலருங் கவிறனளால் தன்மக்கள் பெறுசுரமே
மகவான் கரியானா வது மறவின் சுரமாமே
மஞ்சட்கிணை யானவது மண்ணிற் தொடு கபமே.

ddddddddd- தேரன் வைத்திய மகா கரிசல்.

Quantity, colour, odour, frothy, consistency, indigestion, frequency are noted.
Few patients had, reduced frequency of defecation and passing of hard stools.

7. முத்திரம் (Urine) :

Quantity, colour, odour, frothy, frequency, retention, deposits, presence of abnormal constituents is noted.

நீர்க்குறி:

"வந்த நீர்க்கரி எடை மணம் நுரை எஞ்சலென்
றைந்திய லுளவை யறைகுது முறையே"

-சித்த மருத்துவாங்கச் சுருக்கம்.

The following are observed:

1. Niram - Colouration
2. Edai - Specific gravity
3. Manam - Smell
4. Nurai - Frothy Nature
5. Enjal - Quantity of urine voided.

நெய்க்குறி:

The diagnosis and prognosis of Muthodam, derangement of the disease are studied on the basis of behaviour by drop of gingelly oil on the surface of the urine kept in a wide vessel in the sunlight.

The collected specimen as said above is to be analyzed by following method. The specimen is kept open in a glass dish. It is to be examined under direct sunlight, without any shaking of the vessel. Then add on drop of gingelly oil by at distance of $\frac{1}{2}$ or $\frac{3}{4}$ height, observe keenly the direction in which it spreads within few minutes, and conclude the diagnosis as follows,

"அரவென நீண்டின் அஃதே வாதம்
ஆழிபோல் பரவின் அஃதே பித்தம்
முத்தொத்து நிற்கின் மொழிவதென் கபமே."

If the oil droplet spreads like snake it signifies, vatham; if it spreads like a ring it shows pitham aggravation. The droplet is static as pearl in Kapham derangement.

8. நாடி (Pulse):

"தொகுக்கலுற்ற அட்டவிதப் பரீட்சை தன்னைத்
துலக்கமுறம் பண்டிதரே தெளிவாகப்
பகுக்கரிய நாடியை நீ படித்து பாருப்
பகர்கின்ற வார்த்தையைப் பார் நாவைப் பாரு
வகுக்கரிய தேகமெனத் தொட்டுப் பாரு
வளமான சரீரத்தின் நிறத்தைப் பாரு
சகிக்கரிய மலத்தைப் பார் சலத்தைப் பாரு
சார்ந்த விழிதனைப் பார்த்து தெளிவாய்க் காணே"

-அகத்தியர் வைத்திய வல்லாதி 600

Naadi is a suitable diagnostic tool used by siddhars from the unknown past. It can be felt one inch proximal to the wrist on the radial side by means of palpation with the tip of index, middle and ring fingers corresponding vatham, pitham and Kabam respectively. The three humours Vatham, Pitham and Kabam exists in the ratio 1:1/2:1/4 normally.

Any derangement in the ratio produces disease as in *Thirukural*,

"மிகினும் குறையினும் நோய் செய்யும் வளி
முதலா எண்ணிய மூன்று ".

Examination of the Naadi has been recognized as one of the principle means of diagnosis. But Naadi is not much used for the pediatric diagnosis because considering the physical conditions of the child; naadi can not be understood correctly in children. It is stressed by *Siddha maruthuva chudar* following *Sathaga naadi* verse,

"கொண்டிடவே கயரோகி காச ரோகி
குறிப்பாகச் சிற்றின்பம் செய்த பேர்கள்
அண்டிடவே தரித்திரர்கள் விருத்தர் பாலர்
அன்பாகத் தண்ணீரில் மூழ்கினோர்கள்
கொண்டிடவே இவர்களது உறுப்பின் தாது
கூறவே முடியாது எவர்க்குக் கிட்டும்
பண்டிடவே யிப்பரீட்சை யார்தான் காண்பார்
பராபரத்தின் மகிமையிது பாரு பாரே"
-சதக நாடி.

However, it is always worth trying to assess Nadi in children when it was quite apprehendable. In cases of Virana silethumam, vatha pitham was apprehended commonly followed by Pithakabam and kaba pitham. It correlates with *Paripurana Nadi* as follows,

"விரணமுடன் புண் புரைக்கு வாதபித்தம்"

முக்குற்ற வேறுபாடுகள் (Tri-humoral Derangements):

It is the derangement of three vital Humors (ie) Vatham, Pitham and Kabam.

1. வாதம் (Vatham)

Vatham is a kinetic energy influencing all movements, located in the abanan, idakalai, faeces, spermatic cord, iliac bone, skin, nerves, joints, hair follicles, muscles, bone, ear and thigh.

S.No	Name	Locations	Physiologic Functions
1	Piranan	Heart and Lower and Upper Respiratory Tracts	Controls knowledge, mind and five objects of sense, useful for breathing
2	Abanan	Lower abdomen and extremities	Responsible for urination, expels faeces and foetus, discharge of sperm and menstruation.
3	Viyanan	Mainly at heart	Responsible for movement of all parts of the body and used to feel the sensation
4	Uthanan	Chest	Responsible for vomiting, cough, hiccough, sneezing

5	Samanan	Stomach	Aids for proper digestion. It controls the activity of other vayus
6	Naagan	Eyes	Responsible for opening and closing of the eyes
7	Koorman	Heart and Eyes	Responsible for vision and yawning and controls lacrimation
8	Kirukaran	Throat	Responsible for salivation nasal secretion and appetite
9	Thevathathan	Eruvai & Karuvai	For laziness, sleeping and anger
10	Thananjeyan	Nose	Responsible for bloating of the body after death. It escapes on the third day after death through the cranium when it bursts.

In Virana silethumam, the following are affected,

1. Uthanan: cough, sore throat , difficulty to swallow
2. Samanan : poor control of other vayus
3. Kirukaran : poor appetite, nasal secretion,
4. Devathathan: malaise, sleepiness
5. Abanan : constipation, passing of hard stools

2. பித்தம் (Pitham):

Pitham is the Fuelling energy located in urinary bladder, heart, head, umbilicus, abdomen, blood, sweat, skin and eyes. Pitham is classified into 5 types.

They are,

1. Anal Pitham - Responsible for the digestion of food.
2. Ranjaga pitham - Responsible for the colour of blood.
3. Sathagam - Located in heart and is responsible for normal activities of the body.
4. Alosagam - Responsible for normal vision
5. Prasagam - Responsible for the complexion of skin.

In virana silethumam, the following can be affected

1. Analam – poor appetite
2. Renjagam – pallor of body, conjunctiva , nail bed

3. கபம் (Kabam):

It is the restorative energy that stabilizes, maintains and lubricates all organs. Kabam is found in samanana, semen, brain, head, tongue, nose, bones, bone marrow, fat, nerves, chest, blood, large intestine, eye, stomach and pancreas.

Kabam is classified into 5 types, they are,

1. Avalambagam : Heart is the center for Avalambagam, It controls all other forms of kabam.
2. Kilethagam : Stomach is the center for kilethagam. It gives moisture and softness to the ingested food and helps for digestion.
3. Pothagam : Tongue is the center for pothagam and it is responsible for the sense of taste.

4. Tharpagam : Head is the center for tharpagam. It gives cooling effect to eyes.
5. Santhigam : It lies in the joints and is responsible for the locomotive action of movable bony joints.

Sometimes, pothagam may be affected producing distaste in silethuma diseases.

உடற்கட்டிகள் (7 Physical Constituents):

Udal Kattugal are 7 in number as follows,

1. Saaram : It is the final product of the digestive process, which gives strength to the body and mind.
2. Senneer : Saaram after absorption is converted into senneer. It is responsible for knowledge, strength, boldness, and healthy complexion.
3. Oon : Gives structure and shape to the body and is responsible for the movement of the body.
4. Kozhuppu : Lubricates the organs and proceed on it own works.
5. Enbu : Protects the vital organs and used for movements and nominates the body structure.
6. Moolai : Present inside the bones and it gives strength and maintain the normal condition of the bone.
7. Sukkilam/Suronitham : Responsible for the reproductive functions of the species.

In Virana silethumam, Saaram is affected in all patients and Senneer is affected in some of the patients.

பருவகாலம் (Seasonal Variations):

The whole year is constituted by six seasons. They are,

S.No	Kaalam	Kuttram	State of Kuttram	Suvai
1	Kaar Kaalam (Aavani- Puratasi) (Aug16 – Oct 15)	Vatham ↑↑ Pitham ↑	Vettrunilai Valarchi. Thannilai Valarchi	Enippu Pulippu Uppu.
2	Koothir Kaalam Iypasi – Karthigai (Oct16 – Dec15)	Vatham (–) Pitham ↑↑	Thannilai Adaithal. Vettrunilai Valarchi.	Enippu Kaippu Thuvvarppu
3	Munpani Kaalam (Markazhi – Thai) (Dec16 – Feb15)	Pitham (–)	Thannilai Adaithal	Enippu Pulippu Uppu
4	Pinpani Kaalam (Masi – Panguni) (Feb16 – Apr15)	Kabam ↑	Thannilai Valarchi.	Enippu Pulippu Thuvvarppu

5	Elavenil Kaalam (Chithirai – Vaikasi) (Apr16 – Jun15)	Kabam ↑↑	Vettrunilai Valarchi.	Kaippu Karppu Thubarppu
6	Mudhuvenil Kaalam (Aaani – Aadi) (Jun16 – Aug15)	Vatham ↑ Kabam (–)	Thannilai Valarchi Thannilai Adaithal	Enippu

↑- Thannilai Valarchi ↑↑- Vettrunilai Valarchi (–) - Thannilai Adaithal .

The incidence of viranasilethumam is predominant in Koothir kaalam and Munpani Kaalam. But also occurs in other kaalam, because of life style modification.

According to silethuma roga ilambagam, kabam

- Starts to increase in masi, panguni
- Overflows from actual sites to spread in aadi, aavani, purattasi.
- Reaches its maximum during vaigasi.

ஐந்திணை (FIVE TYPES OF LANDS):

It is divided into five types.

1. Kurinji : Mountain regions and surroundings.
2. Mullai : Forest regions and surroundings.
3. Marutham : Cultivating regions and surroundings.
4. Neithal : Sea and Coastal regions.
5. Palai : Desert land only.

In Kurinji nilam kaba disease are common. In Palai nilam all disease can be caused by deranged vatha, pitha and kaba thodam. Pitha diseases are widely seen in Mullai nilam. Virana silethumam can occur in any nilam since the dietary patterns and habits of the patients can vitiate the Kaba thathu.

உடல் வன்மை (Body Immunity):

Smartness, strength and vitality constitute Udal Vanmai. It is classified into 3 types as

1. Iyarkai Vanmai:

Natural immunity of the body itself by birth.

2. Seyarkai Vanmai:

Improving the health by intake of nutritious food materials, activities and medicines.

3. Kaala Vanmai:

Development of immunity according to age and the environment.

The Vanmai of the children plays an important role in causing the disease and development of recurrent nature. Child's vanmai is affected by mother's deeds during pregnancy, in addition to intake of unwanted foods, unhealthy habits by the child and climatic changes.

மருத்துவம் (Treatment):

“திருந்திய சிலேற்ப ரோக மிருபதுந் தீரவேண்டில்
மருந்தது சதசலோகி நிகண்டினில் வகுத்தார் முன்னோ
ரிருந்திடுஞ் சிலேற்பனத்தி னினமறிந்தருந்துவீரேற்
பொருந்திய சிலேற்பரோகம் புகழறத் தீருங்காணே.”

-தன்வந்திரி வைத்தியம்

The author of the poem recommends that all types of silerpana rogams can be cured if the each type is treated with appropriate medicine after knowing the exact nature of illness.

Siddha treatment is not only for complete healing but also prevention and rejuvenation. The three facets of a vital Siddha therapy involves the following:

1. காய்வு - Prevention:

In any health system, emphasis of “Prevention is better than Cure” is first step in treating a disease. Emulation of healthy diet pattern with sattvic foods, daily habit forms, prophylactic measures to preserve child’s growth and immunity is essential. This forms the basis of parental counselling to strengthen the seyarkai vanmai of the child to prevent deterioration of host immune response to microbial invasion as in case of Virana silethumam. Developing awareness among mothers regarding preventive aspects facilitates reduction in incidence of silethumam diseases among pediatric population.

Prevention methods:

- To avoid chill and cold weather.
- To dress according to weather conditions.
- To avoid eating outside frequently.
- To avoid cold food stuffs, ice creams, etc.
- To avoid contaminated food and water.
- To avoid unhealthy habits like nail biting, thumb sucking, pica etc.
- To find out which agent makes allergy and avoid them.

2. நீக்கம் – Treatment:

Line of Treatment:

The line of treatment as suggested by *PillaiPini Maruthuvam* states:

To neutralize the vitiated Kapham and remove phlegmatic secretions,

- Expectorant
- Stimulants
- Anti-spasmodics can be given.

To relieve fever, sore-throat and headache,

- Febrifuge
- sedatives
- Diaphoretics
- Demulcents can be used.

Siddhars ideology proves meticulous combinations of dry and heat characters with silethumam can neutralise the deranged kabam. This helps in curing grave diseases.

Anupanam in Siddha system:

“அனுபானத்தாலே யவிழ்தம் பலிக்கும்
இனிதான சுக்கு கன்னல் இஞ்சி - பினுமுதகங்
கோமயம் பால்முலைப்பால் கோநெய்தேன் வெற்றிலைநீர்
ஆமிதையா ராய்ந்துசெய லாம்”

-தேரையர் வெண்பா.

Anupanam (Thunai marunthu) is considered vital in siddha without which there cannot be success in treatment. According to dictionary of TVS, vehicle employed goes to modify the quality or active principle of the medicine itself, thus rendering the potency and curative power consistent with the nature of the disease for which it is administered. This point goes synchronous with milk in treating silethuma ailments

Pathiyam:

Pathiyam comprises a list of dietary, habitary pattern that has to be followed to equalize the deranged kuttrams and the restrictions help in enhancement of drug action in addition to favouring quick recovery from the illness.

For patients of kabam disorders, the following are suggested.

“கத்திரி பேய்ப்புடல வரை யிருபாகல் பருங்களா கண்டகாரி
அத்திக் காய்களும் வருக்கைமாபயிற்றை சுரையால் பீர்க்கரும்-பிஞ்சுவேர்
மொய்த்த சூரணங் கதலித் தண்டுகளைப் பூமுளங்கி முருக்கரும்பும்
அத்திப் பூசினிக் காயருள்ளி வள்ளியுங் கபத்தோர்க் காணமாமே.
வேளை மணத்தக்காளி மென் சீதை சக்ரவர்த்தி
பீளை வசலை சுக்கு பெண்சுணங்கள்-வேளையிலை
செந்தளிர் களைக் கீரை செய்வர் கபதேகர் நிதம்
வந்தனியுணத்தான் மகிழ்ந்து.”

-பதார்த்த குண சிந்தாமணி.

Diet Restriction:

- Avoidance of cold drinks, cold food items, cold water, sour fruits like sapota, banana, oranges, lemon, sweet lime, grapes, watery veggies were advised.
- Intake of hot milk with turmeric, pepper and palm candy at nights advised.
- Intake of one among ginger, pepper, thoothuvelai, karisalanganni and manathakkali leaves as rasam, curry, thuvayal or adai was recommended.
- In non-vegetarians, intake of certain varieties of fish, field crab and mutton liver soup were advised.
- In addition, intake of timely, hot easy digestible foods was stressed.

3. நிற்றவு (Restoration):

- Reassurance of disease recovery was given to all patients.
- The children and their parents were advised to follow the essential elements of Siddha dietary, habit pattern and preventive methods to ensure that the illness does not recur.

MODERN ASPECTS

TONSILS AND ADENOIDS

ANATOMY:

The tonsils are pairs of soft tissue masses located at the rear of the throat (pharynx). Each tonsil is composed of tissue similar to lymph nodes, covered by pink mucosa (like on the adjacent mouth lining). Running through the mucosa of each tonsil are pits, called crypts.

WALDEYER RING:

There are superficial masses of lymphoid tissue in the pharyngeal mucosa, which form a ring that acts as a *filter*, protecting the body against infecting organisms that might enter it from the nose or mouth. This ring of lymphoid tissue surrounding the oral and nasal openings into the pharynx is called "Waldeyer's Ring". It includes

- 1) Palatine tonsil
- 2) Pharyngeal tonsil/ adenoid
- 3) Lymphoid tissue surrounding Eustachian tube orifice into the lateral walls of the naso pharynx.
- 4) Lingual tonsil at the base of the tongue
- 5) Scattered lymphoid tissue throughout the remainder of the pharynx but especially behind the posterior pharyngeal pillars and along the posterior pharyngeal wall.

PALATINE TONSIL:

Lymphoid tissue located between the palato-glossal fold (anterior tonsillar pillar) and the palato pharyngeal fold (posterior tonsillar pillar). This is separated from the surrounding pharyngeal musculature by a thick fibrous capsule.

ADENOID:

Single aggregation of lymphoid tissue occupies the space between the nasal septum and the posterior pharyngeal wall. A thin fibrous capsule separates it from the underlying structures. Adenoid does not contain complex crypts that are found in the palatine tonsils but rather simpler crypts.

LINGUAL TONSIL:

Lymphoid tissues at the base of the tongue contain simpler tonsillar crypts.

PHYSIOLOGY:

Approx 65% of the lymphocytes that make up for the Waldeyer Ring are B-Lymphocytes, the remainder being either T-Lymphocytes or plasma cells.

The immunologic role of the tonsils and adenoid is to induce secretory immunity and to regulate the production of secretory immunoglobulins. Situated at the opening of the pharynx to the external environment, the tonsils and adenoid are in a position to provide primary defense against foreign matter. The Deep crevices within tonsillar tissue form tonsillar crypts that are lined with squamous epithelium but have a concentration of lymphocytes at their bases. Lymphoid tissue of Waldeyer Ring is most immunologically active between 4 and 10 years of age, with a decrease after puberty.

Recent studies have indicated the existence of an active cellular defence in the secretion on the tonsillar surface. This defence seems to consist partly of physiologically active neutrophils and is present in health and during disease.

NORMAL FLORA OF MOUTH AND UPPER RESPIRATORY TRACT:

The mouth contains a plethora of organisms-pigmented and non-pigmented micrococci, some of which are aerobic, Gram positive aerobic spore bearing bacilli, coliforms, proteus and lactobacilli. The gum pockets between the teeth and the crypts of the tonsils have a wide spectrum of anaerobic flora – anaerobic micrococci, microaerophilic and anaerobic Streptococci, Vibrios, Fusiform bacilli, Corynebacterium species, Actinomyces, Leptothrix, Mycoplasma, Neisseria hemophilus, Branhamella and

Bacterioides are all found in varying extents. Among fungi, Candida and Geotrichum have been reported.

The mouth of the infant is not sterile at birth. It generally contains the same types of organisms in about the same relative numbers as those present in the mother's vagina that is a mixture of Micrococci, Streptococci, Coliform bacilli and Doderlein's bacilli. These organisms diminish in number during the first 2-5 days after birth and are replaced by the types of bacteria present in the mouth of the mother and nurse.

Within 12 hours after birth alpha hemolytic streptococci are found in the upper respiratory tract and become the dominant organisms of the oropharynx and remain so for life. In the pharynx and trachea, flora similar to that of mouth establishes themselves. Few bacteria are found in normal bronchi. Smaller bronchi and alveoli are normally sterile.

The commensals from the normal flora of the mouth, nasopharynx may get into the blood and tissues. They are usually quickly eliminated by the normal defence mechanism of the body; occasional diphtheroids or non-hemolytic streptococci from normal and abnormal lymph nodes may be those which escaped elimination. Unless the organisms of doubtful pathogenicity are isolated more than once in serial blood cultures, they have little significance.

PATHOLOGY:

ACUTE INFECTION:

Most episodes of acute pharyngotonsillitis are caused by viruses such as Adenovirus, coronavirus, enterovirus, rhinovirus, respiratory syncytial virus (RSV), Ebstein Barr Virus, Herpes Simplex Virus and Metapneumo virus. Next to viral infections, GABHS is being the most common cause of bacterial infection in the pharynx. Additional bacterial organisms can include other beta-hemolytic streptococci, Group C, Staphylococcal aureus, gram negative organisms, Mycoplasma pneumoniae, Neisseria gonorrhoea and Corynebacterium diphtheriae.

Oral candidiasis can occur in immunocompromised children who have been treated chronically with antibiotics or inhaled steroids.

CHRONIC INFECTION:

Occurs by multiple microbes, which include high incidence of beta-lactamase producing organisms such as;

Aerobic: Streptococci, H.influenzae,

Anaerobic: Peptostreptococcus, Prevotella, Fusobacterium predominate etc.

TONSILLAR CRYPTS:

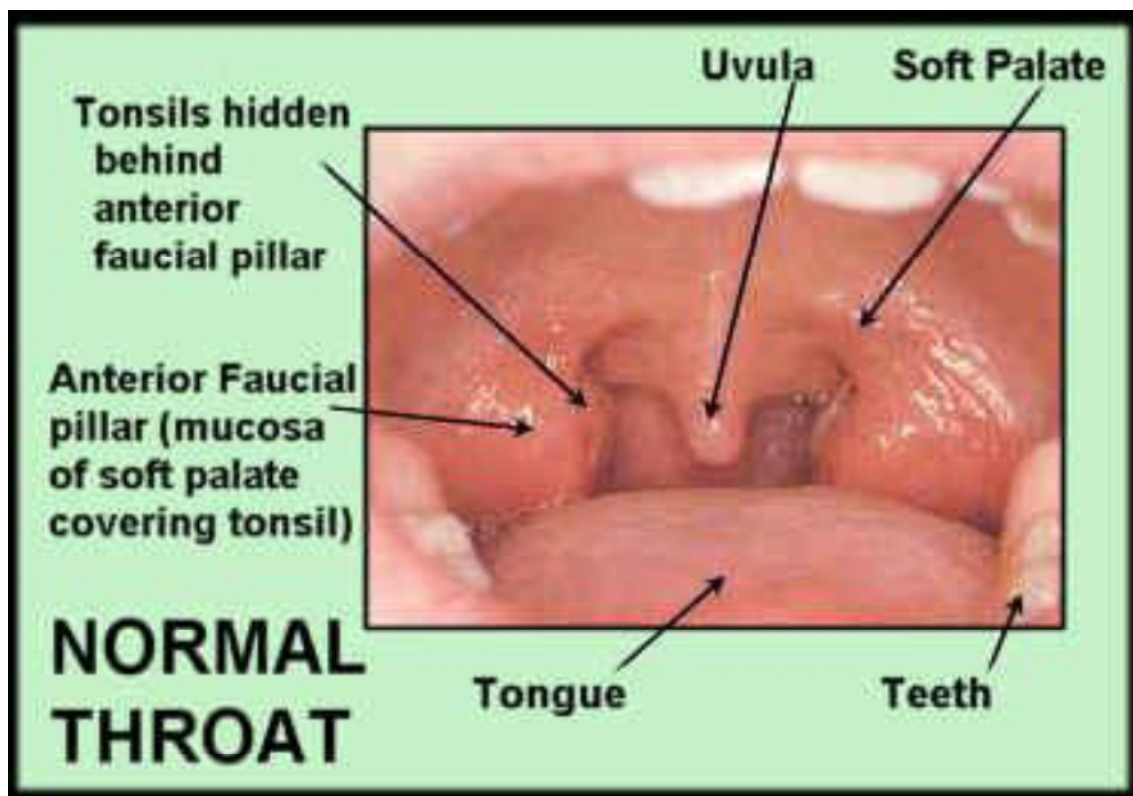
The accumulated desquamated epithelial cells, lymphocyte, bacteria and other debris cause cryptic tonsillitis. These cryptic plugs can calcify into tonsillar concretions or tonsilloliths.

AIRWAY OBSTRUCTION:

Both the tonsil and adenoid hypertrophy are a major cause of upper respiratory tract obstruction in children.

TONSILLAR NEOPLASM:

Rapid enlargement of one tonsil is highly suggestive of a tonsillar malignancy, typically lymphoma in children.



Normal Healthy Throat and Airway.



Enlarged Crowded Tonsils.

Acute Pharyngo-tonsillitis



Tonsillitis with exudates

ACUTE PHARYNGOTONSILLITIS

DEFINITION:

Acute inflammation generally restricted to the tonsils, posterior pharynx, uvula, posterior palate and the lymph nodes of the Waldeyer's lymphatic ring that drain the anterior cervical region. Acute pharyngotonsillitis is an infection restricted to the crypt and surface secretion. When referring to tonsillitis, the correct term is pharyngo-tonsillitis (PT) as the pharynx has lateral cords with the same type of tissue as in Waldeyer's lymphatic ring.

In previous studies on acute pharyngotonsillitis, it is found that the secretion in crypts and at the surface was infected in acute pharyngotonsillitis while no bacteria were detected in the parenchyma. Based on these results, researchers have proposed a new hypothesis stating that the infection is restricted to the crypt and surface secretions in acute pharyngotonsillitis.

EPIDEMIOLOGY:

In a survey involving 429 pediatricians in the United States, Upper respiratory tract infections and ear infections were the most common causes for a visit. Pharyngo-tonsillitis was the third most common problem, responsible for 17 % of the visits, according to the age of the child.

PREVALENCE AND DISTRIBUTION:

GAS most often affects children and young adults (5-15 years of age). Infection is most common during the winter and early spring. GAS is the cause of approximately 15-30% of acute pharyngo-tonsillitis in children and 5-10% in adults⁷.

ETIOLOGY:

VIRAL:

Adenovirus, Rhinovirus, Coxsackie viruses A & B, influenza virus, Para influenza virus, Echo virus and Respiratory Syncytial virus and Epstein Barr virus.

BACTERIAL:

Usually caused by Group A Beta-Hemolytic streptococci. Less common pathogens include *S.aureus*, *H.influenzae*, *M.catarrhalis*, *Diphtheriae*, *Gonococci*, *chlamydiae*.

Mycoplasma pneumoniae and *Candida albicans* have also been incriminated.

Irritant fumes and smoke also cause irritation of the throat.

MICROBIOLOGY:

In a study, about 54% of the patients⁸, an initial throat swab did not grow any pathogenic organism. Positive swabs were mostly of GABHS or *Staphylococcus aureus*. Group A -haemolytic streptococcus (GABHS) is one of the major causes of tonsillitis. However, other aerobic and anaerobic organisms can be isolated from the surface and core of normal and inflamed tonsils. The exact role of these organisms is uncertain, and some are believed to be part of the normal oropharyngeal flora, as we saw earlier. Anaerobic bacteria predominate in the normal oral flora, outnumbering aerobic bacteria in a ratio of 10:1.

- GABHS is the best known cause of pharyngotonsillitis,
- Occasionally, groups B, C and G beta-hemolytic streptococci are responsible, *Streptococcus pneumoniae* infections may be self-limited or it may spread to other sites.
- *Corynebacterium diphtheriae* produces a lethal exotoxin that is absorbed from the site of infection and carried to other organs, such as the throat, palate, and larynx.

- *Arcanobacterium hemolyticum* infection affects the 15-18-year age group and accounts for 2.5- 10% of all cases of pharyngotonsillitis.
- *Neisseria gonorrhoeae* infection is more common in homosexual males and may be associated with pharyngitis in adolescents. It can result in bacteremia and may persist after treatment.
- *Neisseria meningitidis* can cause symptomatic or asymptomatic pharyngotonsillitis which can be a prodrome for septicemia or meningitis.
- *Staphylococcus aureus* is often isolated from chronically inflamed tonsils and peritonsillar abscesses. The bacterium produces betalactamase which can interfere with the eradication of GABHS.
- Nontypable *H. Influenzae* and *H. parainfluenzae* may be recovered from inflamed tonsils. These agents can cause invasive disease in infants and the elderly, as well as acute epiglottitis, otitis media, and sinusitis. High tissue concentrations of *H. Influenzae*, *Staphylococcus aureus* and GABHS correlate with clinical parameters of recurrent infection and hyperplasia of the tonsils.
- In rare cases, pharyngotonsillitis is caused by *Francisella tularensis*, *Treponema pallidum*, *Mycobacterium* spp, or *Toxoplasma gondii*.
- The anaerobic species that have been implicated in pharyngotonsillitis are *Actinomyces*, *Fusobacterium*, and gram negative bacilli (e.g. pigmented *Prevotella* and *Porphyromonas* spp. and *Bacteroides* spp.). The role of anaerobes is supported by their predominance in tonsillar or retropharyngeal abscesses and Vincent's angina (*Fusobacterium* spp. and spirochetes). Elevated serum levels of antibodies to *Prevotella intermedia* and *Fusobacterium nucleatum* have been found in patients with recurrent non-GABHS tonsillitis and peritonsillar cellulitis and abscess.
- *Mycoplasma pneumoniae* and *Mycoplasma hominis* can also cause pharyngotonsillitis, usually as a manifestation of a generalized infection. The prevalence of *Mycoplasma* infection increases with age.
- *Chlamydiae pneumoniae* infection often accompanies pneumonia or bronchitis.

PRECIPITATING FACTORS :

In children, history of attacks is precipitated by intake of cold drinks (aerated drinks as well as juice), ice-creams, fried items and passive smoking. These factors could possibly be acting by

- Altering the bacterial micro flora and/or
- Lowering host immunity by altering local factors in the throat.

TRANSMISSION:

Major source of the streptococcus pyogenes is the human upper respiratory tract ie. Throat, nasopharynx or nose of the patients and carriers. Nasopharynx and oropharynx are the main sites of colonization. Carrier rates of up to 20% have been observed.

Aerosol secretions of the upper respiratory tract are the primary transmitting source of the causative agents. Transmission is either by direct contact or through contaminated fingers, dust or fomites.

Risk of contagion depends on the amount that was inoculated and on the virulence of the strain. Thus, individuals are more prone to become infected in the early stages of disease. Crowding is an important factor in the transmission of infection. Outbreaks of infection may occur in closed communities such as boarding schools or day care centers.

The incubation period is from 1 to 4 days and most physicians allow children to go back to school 48 to 72 hours after the antimicrobial treatment is started. The rate of transmission of GAS in untreated patients is approximately 35% in close contacts, such as family members or schools.

GENERALISED CLINICAL FEATURES:

Irrespective of the type of Pharyngotonsillitis, the following are the classical features

Symptoms

- Odynophagia,
- sorethroat,
- malaise, fever and chills,
- dysphagia,
- referred otalgia,
- headache,
- muscular aches and
- enlarged lymph nodes.

Signs

- Dry tongue,
- Erythematous enlarged tonsils,
- Tonsillar/pharyngeal exudates,
- Palatine petechiae,
- Enlargement & tenderness of jugulo-digastric lymphnodes.

VIRAL PHARYNGOTONSILLITIS:

The predominance of viral infections is very high in children younger than 3 years of age, an age group where pharyngo-tonsillitis caused by GABHS is rare. The onset is gradual and there is less toxaemia. An irritation of the pharynx / tonsils is frequently found with viral infections.

Children with viral infections often have extra-pharyngeal signs and symptoms, as nasal secretions, conjunctivitis, cough, hoarseness, diarrhea, ulcerations or other clinical manifestations highly suggestive of viral infections.

It presents with grayish or yellowish white discrete areas of exudate on tonsils with pharyngeal erythema and tender cervical lymphadenopathy.

The classical symptoms of viral infections namely, cough, rhinitis, conjunctivitis, and diarrhea, are usually absent in bacterial pharyngotonsillitis. (According to the clinical index developed by McIsaac and colleagues)

BACTERIAL PHARYNGOTONSILLITIS :

GABHS has been the most common cause of acute pharyngotonsillitis, its importance not only lies in the frequency but due to its serious sequelae ie, acute rheumatic fever and post streptococcal glomerulonephritis.

The onset is sudden, acute, characterised by odynophagia, high fever, headache and abdominal pain.

Signs and symptoms of pharyngotonsillitis caused by GABHS can vary from mild pain in the throat and malaise (30% to 50% of cases) to high fever, nausea, vomiting and dehydration (10% of cases).

The mucosa in the pharynx and tonsils is typically hyperemic, with occasional edema, exudate being present in 50% - 90% of the cases.

Petechiae or doughnut lesions on the soft palate or posterior pharynx. Uvula is red, stippled and swollen.

Cervical adenopathy is very common (30% - 60% of cases). When present in the classical form, the scarletiform exanthema is very indicative of a bacterial infection, but is not frequent. GABHS pharyngotonsillitis tends to present with exudative pharyngitis.

Younger children may not complain of sorethroat but often refuse to feed normally.

COURSE OF ILLNESS:

Viral pharyngotonsillitis is usually associated with nasal secretions and is generally self-limited (4-10 days), whereas bacterial illness, if left untreated, lasts longer.

DIAGNOSIS:

Most infections around waldeyer's ring are polymicrobial in nature and often it is difficult in interpreting data of samples and differentiating between the organisms that are colonized and those that are invaders. Several studies have documented that most physicians empirically start antimicrobial therapy for suspected acute pharyngitis and may not collect a swab for throat culture¹⁰.

1. Complete Blood Count (CBC): Neutrophil count in the peripheral blood is elevated in streptococcal infections.
2. An increase in antistreptolysin O (ASO) streptococcal antibody titer after 3-6 weeks can provide retrospective evidence of GABHS infection. The usual test done is anti streptolysin O titration. ASO Titres > 200 are indicative of prior streptococcal infection.
3. High CRP value is seen in streptococcal infections. In patients with streptococci group C or G an elevated CRP-value was significantly associated.
4. Culture from the tonsils, tonsil crypts or pharynx : was earlier considered as golden standard for the definite etiologic diagnosis of a Pharyngo tonsillitis (due to 95% specificity in GABHS identification) but now judged to be an imperfect gold standard for diagnosing streptococcal pharyngitis because of the following:
 - a. False positive cultures can occur if the organisms are misidentified as GABHS.
 - b. Children who are streptococcal carriers can also have positive cultures.
 - c. False negative cultures are attributed to a variety of causes including inadequate throat swab specimens and patients surreptitious use of antibiotics.
5. Rapid Streptococcal antigen detecting test: Gives result within 10 minutes. The specificity is high. If rapid test is positive, indicates appropriate treatment.
6. If rapid strep test is negative, confirmation with throat culture is considered mandatory on account of clinical suspicion of GABHS.

7. Viral cultures often unavailable. It is too expensive and too slow to be clinically useful.
8. Viral Polymerase Chain Reaction (PCR): more rapid and may be useful but not always necessary.
9. Monospot or Paul-Bunnell Test or Slide Agglutination test: helps confirm EBV infectious mononucleosis.
10. A lateral soft tissue X ray film of the Head and Neck region will show up the hypertrophic tonsils and adenoids together with narrowing of naso and oropharynx.

Short duration of symptoms, considerable pain on swallowing, an age of 3 to 14 years, an elevated CRP value and four Centor criteria (fever, anterior cervical lymphadenopathy, tonsillar rubor and exudates, and lack of cough) are of significant value in diagnosing streptococcal pharyngotonsillitis.

For tonsillar hypertrophy, the following scale is usually used in clinical practice.

Size & Percentage of Obstruction:

1. GRADE 0 : tonsil is in fossa
2. GRADE 1 : less than 25% obstruction
3. GRADE 2 : less than 50% obstruction
4. GRADE 3 : less than 75% obstruction
5. GRADE 4: more than 75% obstruction.

In adults, the Centor criteria are most often used. The 4 criteria are:

1. Tonsillar exudates;
2. Tender anterior cervical adenopathy;
3. Fever by history;
4. Absence of cough.

Persons with three or four of these criteria may be treated empirically for GAS. Those with zero or one criterion do not need to be tested or treated. If two or three criteria are present, testing should be performed and patients treated only if the test is positive.

The *McIsaac modification of the Centor criteria* is being used nowadays in children. Points for a patient are added based on the following scoring:

1. history of fever or $T > 101^{\circ}\text{F}$ (38.0°C) +1
2. absence of cough +1
3. tender anterior cervical adenopathy +1
4. tonsillar swelling or exudates +1
5. age < 15 years +1
6. age ≥ 45 years -1

Children with 0 points are unlikely to have GAS infection and do not need to be tested. Those with 1-3 points should be tested and treatment based on the test result. Those with 4-5 points have a high likelihood of having GAS infection and may be treated empirically or tested and treated if the test is positive.

ASSESSMENT:

The improvement in case of pharyngo-tonsillitis can also be assessed by the improvement in the symptoms such as difficulty in feeding in small children, mouth breathing, noisy respiration, loud snoring, frequent awakening or hypersomnolence, secondary enuresis, night terrors or changes in behaviour pattern (Pavor Nocturnus).

Regular monitoring of the improvement in the symptomatology proves to provide clue for clinical prognosis and assessment of management.

DIFFERENTIAL DIAGNOSIS:

1. Narrowing and spasm of trachea and bronchi may also cause sensation of sorethroat with a constant desire to clear the throat.
2. Primary HSV infections in young children often present as high fever and gingivostomatitis but pharyngitis may be present.
3. Herpangina: it is an acute febrile illness due to the group 'A' Coxsackie virus. Patients have dysphagia, sorethroat and papulovesicular lesions surrounded by erythema over the tongue, pharynx, anterior tonsillar pillars and soft palate. Pharynx appears congested with the presence of small yellowish white nodules.
4. Diphtheria: *Corynebacterium diphtheriae* infection causes a bull neck and an early exudative pharyngotonsillitis characterized by the development of a grayish-green thick membrane that is difficult to dislodge, and when torn off, often leaves a bleeding surface. Associated moderate fever and toxemia are present.
5. Agranulocytosis: Blood count shows neutropenia.
6. Pharyngoconjunctival fever: patients have fever, conjunctivitis, pharyngitis and cervical lymphadenitis due to infection with adenovirus type III.
7. Infectious mononucleosis: Characterised by lymphadenopathy, morbilliform rash, hepatosplenomegaly, generalized fatigue and sometimes aseptic meningitis. Massive cervical lymphadenopathy gives the characteristic "Bull-neck" appearance.

8. Gonococcal pharyngeal infections are usually asymptomatic though some exhibit pharyngeal ulcers or exudates. It can cause acute pharyngitis with fever and cervical lymphadenitis.
9. Mycoplasma pneumoniae infection occurs only in early adolescence.

COMPLICATIONS:

Many of the pharyngotonsillitis complications include the obstructive, infectious, toxin-mediated or immunomediated.

OBSTRUCTIVE:

Patients with tonsillar hyperplasia can have breathing difficulties, in general when the acute tonsillar inflammation leads to edema. In certain infections, as caused by the Epstein Barr virus, the degree of edema can be so severe that tonsils that are generally non obstructive can interfere with breathing. This is typically manifested in sleep-disordered breathing including Obstructive sleep apnea, Hyperpnoea and upper airway resistance syndrome.

INFECTIOUS:

This includes both suppurative and non-suppurative. Streptococcus pyogenes infections lead to two important **non-suppurative** sequelae.

- **Acute glomerulo-nephritis (AGN):** the acute nephritic syndrome can develop 1 to 2 weeks after an acute streptococcal infection and complicates approximately 5% of cases of GABHS pharyngitis in children. The early administration of antibiotics does not prevent this sequela. The most frequent form of AGN is the IgA-mediated nephropathy, associated with chronic tonsillitis.
- **Acute Rheumatic fever (ARF):** it is the most serious infectious complication of the acute streptococcal Pharyngotonsillitis. ARF happens in < 3% of untreated cases of GAS during an epidemic and in < 0.5% of sporadic cases. It ensues 1 to 3 weeks after the acute infection so that the organism may not be detectable when

sequelae set in. this clinical entity presents with triad of arthritis, carditis and chorea. It can also lead to a heart valve disease ie, mitral stenosis.

From the throat, streptococci may invade to the surrounding tissues, leading to **suppurative** complications such as

- Otitis media
- Sinusitis.
- Peritonsillar abscess is the most common infectious complication resulting from an extensive acute exudative tonsillitis.
- Retropharyngeal or parapharyngeal abscesses.
- Mastoiditis
- Quincke
- Ludwig's angina
- Suppurative cervical adenitis.
- Supraglottitis
- Cellulitis
- Fasciitis
- Peritonitis
- Arthritis
- Osteomyelitis
- Thyroiditis
- Meningitis
- Bacteremia
- The infection may spread down the tracheobronchial tree causing tracheobronchitis and pneumonia.

Therapy with antibiotics can prevent the above suppurative complications and rheumatic fever among non-suppurative complications. However, a final conclusion has not been reached yet about post-streptococcal acute glomerulonephritis being prevented by antibiotic therapy.

TOXIN-MEDIATED:

- Scarlet fever is a classical, toxin-mediated form of infection by GABHS
- Another toxin mediated disease associated with GABHS is the necrotizing fasciitis or Toxic shock syndrome.
- Recently a new syndrome called PANDAS (Pediatric Autoimmune Neuropsychiatric Disorder Associated with Group A Streptococci) has been described. The syndrome involves obsessive-compulsive disorder or tic disorder with other neurologic abnormalities of abrupt onset in association with GABHS infections. A clear cut relationship between the syndrome and GABHS infection is yet to be published.

TONSILLECTOMY:

The most followed curative treatment nowadays is surgical removal of tonsils.

Adenoidectomy & Tonsillectomy are currently one among the top 10 pediatric surgeries.

In the first century AD, Celsus described tonsillectomy performed with sharp tools and followed by rinses with vinegar and other medicinals. Since that time, physicians have been documenting surgical management of tonsillitis.

INDICATIONS FOR TONSILLECTOMY:

The current clinical indications for tonsillectomy are:

(As recommended by the AAO-HNS in 2000)

- An important indication is recurrent or chronic pharyngo-tonsillitis.
- 3 or more infections per year despite adequate medical therapy.
- Hypertrophy causing dental malocclusion or adversely affecting oro-facial growth documented by orthodontist

- Hypertrophy causing upper airway obstruction, severe dysphagia, sleep disorders (obstructive sleep apnea)
- Unilateral tonsil hypertrophy presumed to be neoplastic.
- cardiopulmonary complications
- Peritonsillar abscess unresponsive to medical management and drainage documented by surgeon (except when surgery is performed during acute stage)
- Persistent foul taste or breath due to chronic tonsillitis not responsive to medical therapy;
- Previous peritonsillar abscess may be a relative indication.
- Significant missed time from school or work should prompt for tonsillectomy.

DEMERITS OF TONSILLECTOMY:

- Tonsillectomy and adenoidectomy results in a major loss of pharyngeal lymphoid tissue.
- Dehydration from odynophagia is common in the first post operative week.
- Immunization against poliomyelitis in post-tonsillectomy patients has a higher incidence of bulbar poliomyelitis.
- Swelling of the tongue and soft palate may lead to acute airway obstruction in the first few hours after surgery. Children with underlying hypotonia or craniofacial anomalies are at greater risk of suffering this complication

- Bleeding may occur in the immediate post-operative period or be delayed after separation of eschar. Postoperative hemorrhage is considered the most significant risk.
- Rare complications include velopharyngeal insufficiency, nasopharyngeal or oropharyngeal stenosis
- Psychological problems.
- Tonsillectomy has not shown to offer clinical benefit over conservative treatment in children with mild symptoms. Furthermore, tonsillectomy does not prevent recurrence of pharyngeal infections.
- No significant difference exists between the type and number of pathogens in patients undergoing adenotonsillectomy for recurrent infection or obstruction^{24&25}.

CARRIERS:

Patients exposed to GABHS can continue to asymptotically “carry” the organism, even after an appropriate antimicrobial therapy. Carriers are recognized as individuals that have a positive culture for this organism, although there is a very low risk that they will transmit GABHS or even develop sequelae. The rate of carriers reported in the literature varies from 3 to 40% depending upon the population being assessed.

TREATMENT:

Most untreated episodes of Streptococcal pharyngo-tonsillitis resolve uneventfully in a few days, but early antibiotic therapy hastens clinical recovery by 12 to 24 hours. The treatment should be aimed at relieving symptoms of the acute disease (antipyretics, analgesics), eliminate transmissibility; prevent both suppurative and non-suppurative sequelae. When selecting an antimicrobial for treatment of group A

streptococcal pharyngo-tonsillitis, important issues to consider include efficacy, safety, antimicrobial spectrum (narrow vs. broad), dosing schedule, associated compliance with therapy (i.e., adherence) and cost. These factors influence the cost-effectiveness of antimicrobial therapy.

RECURRENT EPISODES OF PHARYNGOTONSILLITIS:

The criteria is

- 7 or more throat infections treated with antibiotics in the preceding year
- 5 or more throat infections treated in each of the preceding two years
- 3 or more throat infections treated with antibiotics in each of the preceding three years.

In order to control the recurrency, following strategies are to be followed:

- Smoky and dusty atmosphere should be avoided.
- Dampness in the environment and overcrowding are to be better avoided.
- Child's general health should be improved by good nutritious diet.
- A detailed history should be obtained and physical examination conducted for proper evaluation.
- Paranasal sinuses and ears should be examined for the foci of infection and if present, should be adequately treated.

DRUG REVIEW

(PROPERTIES OF TRIAL DRUG INGREDIENTS)

கொத்துமல்லி

Botanical Name: *Coriandrum sativum*, Linn

Classical /Vernacular Names: உருள்அரிசி, தனியா

Natural Order: Apiaceae

சுவை: கார்ப்பு

தன்மை: சீத வெப்பம்

பிரிவு: கார்ப்பு

செய்கை: வெப்பமுண்டாக்கி, அகட்டுவாய்வகற்றி, பசித்தீதுண்டி, சிறுநீர்பெருக்கி

குணம்:

கொத்துமல்லி வெப்பம் குளிர்காய்ச்சல் பித்தமந்தஞ்

சரத்திவிக்கல் தாகமொடு தாதுநட்டம்-கத்தியெழும்

வாத விகார்மடர் வன்கர்த்த பிவிரணம்

பூதலத்தில் லாதகற்றும் போற்றும்.

- அகத்தியர் குணவாகடம்.

Botanical Description:

Fruits yellowish brown, globose, 4-5 mm in diameter, ribbed, separating into two halves. Seeds compressed.

Parts Used: Whole plant, fruit

Pharmacognosy:

Fruits is subglobose, glabrous, schizocarp, about 5 mm in diameter, splitting into two hemispherical mericarps. Each mericarp has 5 wavy, rather inconspicuous, primary ridges alternating with 4 more prominent secondary ridges.

Physical Constituents:

- Total ash: not more than 6%
- Acid insoluble ash: not more than 1.5%
- Alcohol soluble extract: not less than 10%
- Water soluble extract: not less than 19%
- Volatile oil: not less than 0.3%.

Chemical Constituents:

D-mannitol, flavonoid glycosides, coriandronediol, quercetin-3-O-caffeoyl-glucoside, kaempferol 3-glucoside,, limonene, borneol, caryophyllene, thymol, geranyl acetate.

Pharmacological Activity:

Anti-microbial, spasmolytic.

Extract of seed shows fungitoxic effect against *Helminthosporium oryzae*.

Coriander sativum which was commonly used flavouring agent in food. The essential oil from coriander was found to have antibacterial activity (Silva et al, 2011). Also safety assessment of coriander showed no toxic effects (Burdock et al, 2009).

சன்னலவங்கப்பட்டை

Botanical Name: *Cinnamomum verum, Presl*

Classical /Vernacular Names: கருவாப்பட்டை

Natural Order: Lauraceae

சுவை: காரமும் இனிப்புடையது

தன்மை: தட்பம்

பிரிவு: இனிப்பு

செய்கை: வெப்பமுண்டாக்கி, அகட்டுவாய்வகற்றி, காமம்பெருக்கி

குணம்:

தாதுநட்டம் பேதி சருவிஷமும் ஆகியநோய்

பூதகிர கஞ்சிலந்திப் பூச்சிவிட -சாதிவிடம்

ஆட்டுமிரைப் போடிருமல் ஆகியநோய்க் கூட்டமற

ஓட்டுமில வங்க துரி.

- அகத்தியர் குணவாகடம்.

Botanical Description:

An evergreen tree, 8-16m high, with reddish brown bark having numerous small warts.

Parts Used: Bark

Pharmacognosy:

Bark pieces are about 0.5 mm thick, brittle; outer surface dull yellowish-brown, marked with pale wavy longitudinal lines with occasional small scars or holes; inner surface darker in colour, striated with longitudinally elongated reticulation;

Odour fragrant; taste sweet, aromatic.

Physical Constituents:

- Total ash: not more than 3%
- Acid insoluble ash: not more than 2%
- Alcohol soluble extract: not less than 2%
- Water soluble extract: not less than 3%
- Volatile oil: not less than 1%.

Chemical Constituents:

Cinnamaldehyde, eugenol, benzaldehyde, cymene, cumic aldehyde, linalool, benzyl acetate, cinnamic aldehyde, eugenyl acetate, cinnamyl acetate, benzyl benzoate, cinnassiol C1 glucoside, cinnassiol C2 and cinnassiol C3, cinnassiol D1, its glucoside.

Pharmacological Activity:

Anti-microbial, Antiallergic, Anti-complement, Anti-Fungal, Anti-oxidant, Antinociceptive

இலவங்கம்

Botanical Name: *Syzygium aromaticum* (Linn) Merrill & Perry

Synonyms:

Eugenia caryophyllata Thunb.

Eugenia aromaticum Kuntze.

Caryophyllus aromaticus Linn.

Classical/Vernacular Names:

அஞ்சுகம், உற்கடம், கருவாய்க் கிராம்பு, சோசம், திரளி, வராங்கம்.

Natural Order: Myrtaceae

சுவை: காரமும், விறுவிறுப்புமுள்ளது;

தன்மை: வெப்பம்

பிரிவு: கார்ப்பு

செய்கை:

இசிவகற்றி, அகட்டுவாய்வகற்றி, பசித்தீத்தூண்டி.

குணம்:

பித்தமயக்கம் பேதியொடு வாந்தியும்போம்

சுத்தவிரத் தக்கடுப்புந்தோன்றுமோ- மெத்த

இலவங்கங் கொண்டவருக் கேற் சுகமாகும்

மலமங்கே கட்டுமென வாழ்த்து.”

“சுக்கில நடட்டங்கர்ண சூர்வியங்க லாஞ் சனந்தாட்

சிக்கல்விடாச் சர்வா சியப்பிணியு-மக்கிக்குட்

டங்கப் பூவோடு தரிபடருந் தோன்றியில்

வங்கப்பூ வோடுரைத்து வா”.

- அகத்தியர் குணவாகடம்.

- தணலில் வதக்கி, வாயிலிட்டுச் சுவைக்க தொண்டைப் புண் ஆறும்.
- இலவங்கத் தைலம்: அழுகலகற்றி, உணர்ச்சி போக்கி செய்கையுடையது.

Botanical Description:

Flower buds: Greenish to pink, aromatic, clustered at the ends of branches

Parts Used: Flower buds, oil

Pharmacognosy:

Flower bud is 10-17.5mm long; dark brown/dusty red colour, consisting of a sub-cylindrical, slightly flattened, four sided hypanthium, readily exuding oil when pressed. Odour is strongly aromatic; taste pungent, aromatic followed by slight tingling of the tongue. Clusters of calcium oxalate crystals are present in stalk.

Physical constituents:

- Foreign matter: not more than 2%
- Total ash: not more than 7%
- Acid insoluble ash: not more than 1%
- Alcohol soluble extract: not less than 3%
- Water soluble extract: not less than 9%
- Volatile oil: not less than 15%

Chemical constituents:

Isobiflorin, Biflorin(Flower bud),

Eugenol, Acetyl eugenol, Eugenilin, Eugenone , Eugenol acetate, Eugenine

Eugenitone, Isoeugenitol (clove oil)

Caryophyllene, Epoxydihydrocaryophyllene, Ellagitannin- Syzyginins A, Syzyginins-B (leaves).

Pharmacological activity:

Anti-fungal, antiviral, antibacterial, cholagogue, antimicrobial, anticarcinogenic, radical scavenging activity, histamine release inhibitory activity.

Syzygium aromaticum widely used spice in food. Eugenol was found as major component in clove

Antibacterial Activity of Eugenol: A crude MeOH extract of *Syzygium aromaticum* (clove) exhibited preferential growth-inhibitory activity against Gram-negative anaerobic periodontal oral pathogens, including *Porphyromonas gingivalis* and *Prevotella intermedia*. Eugenol was found to be potent bactericidal component in essential oil extracts, against fastidious and facultative anaerobic oral bacteria. Eugenol was also found that a synergistic antimicrobial effect with erythromycin.

Anti-Viral Effects: Eugenol found in clove and bay oils [Clove oil is the greatest source of eugenol (70.9% eugenol)] have virucidal effects as it is reported to inhibit herpes virus replication in vitro.

Anti-Fungal Effects: Eugenol displayed potent activity against *C. albicans* biofilms in vitro with low cytotoxicity and therefore has potential therapeutic implication for candidal infections.

Anaesthetic action of Eugenol: Molecular mechanism for local anesthetic action of eugenol in the trigeminal system is identified.

Antipyretic action of eugenol: The analgesic agent eugenol reduced fever when given intravenously in small doses. Eugenol was more effective in reducing fever than acetaminophen.

Antioxidant action of eugenol: Free radical scavenging activity, metal chelation and antioxidant power as shown by the higher DPPH radical scavenging activity of Cloves followed by cardamom ingredients of the trial drug Malli chooranam. Eugenol and its derivatives are responsible for potent anti-oxidant action.

Clove exerted immunomodulatory/anti-inflammatory effects by inhibiting LPS action. A possible mechanism of action probably involved the suppression of the nuclear factor- κ B pathway by eugenol, since it was the major compound found in clove extract (Bachiega TH et al, 2012).

Substitutes and adulterants:

Mother of cloves, clove stems, exhausted cloves, withered cloves, clove dust containing broken stamens, farinaceous products, cereal starches, ground fruit, unripe fruits of *Cinnamomum verum* J. S. Presl.

The biological activity of *Eugenia caryophyllata* has been investigated on several microorganisms and parasites, including pathogenic bacteria, Herpes simplex and hepatitis C viruses. In addition to its antimicrobial, antioxidant, antifungal and antiviral activity, clove essential oil possesses antiinflammatory, cytotoxic, insect repellent and anaesthetic properties.

ஏலம்:

Botanical Name: *Elettaria cardamomum* Linn

Classical /Vernacular Names: ஸ்ரீஞ்சி, கோரங்கம், துடி

Natural Order: Zingiberaceae

சுவை: கார்ப்பு

தன்மை: வெப்பம்

பிரிவு: கார்ப்பு

செய்கை: வெப்பமுண்டாக்கி, அகட்டுவாய்வகற்றி, பசித்தீதுண்டி.

குணம்:

“தொண்டை வாய்கவுள் தாலுகுதங்களில்

தோன்றும் நோயதி சாரம்பன் மேகத்தால்

உண்டை போலெழும் கட்டி கிரிச்சரம்

உழலை வாந்தி சிலந்தி விஷச்சரம்

பண்டை வெக்கை விதாக நோய் காசமும்

பாழுஞ் சோமப்பிணி விந்து நட்டமும்

அண்டை யீளைவன் பித்தம் இவைகெல்லாம்

ஆல மாங்கமழ் ஏல- மருந்ததே”

- தேரையர் குணவாகடம்.

தொண்டை, தாள், வாய், கீழ் வாய் இவைகளில் உண்டாகும் நோய்களையும், இருமல், நெஞ்சின் கோழை கட்டு, கழிச்சல் இவற்றையும் போக்கும். அழலை ஆற்றும்.

“மல வாதமோடு வயிற்றுக் கொதிப்பு

சலமுறல் வாயினிப்பு தாகஞ் சலபேதி

வேர்க்குந் தலை நோய் மிகுருட்சை யையமிவை

போக்குஞ்சிற் றேலம் புகல்”

- அகத்தியர் குணவாகடம்.

வாய் நீருறல், நீர் வேட்கை, வேர்வையுடன் கூடிய தலைவலி, மிகுந்த வறட்சி, கபம் இவைகளை போக்கும் இயல்புடையது.

Botanical Description:

Fruits trilocular, subglobose or fusiform to ovoid capsule, brownish black, angled, rugose, covered with a thin mucilaginous membrane.

Parts Used: Fruits, Seeds

Pharmacognosy:

Fruit: 1-2 cm long, ovoid, oblong, more or less three sided with rounded angles; greenish to pale or yellowish in colour, surface with longitudinal striations; fruit trilocular; each fruit containing about 10-15 seeds in a row of doubles. Seeds are dark brown to black, transversely wrinkled; odour strongly aromatic, taste characteristic.

Perisperm is of thin walled cells packed with rounded polyhedral starch grains and containing prismatic crystals of calcium oxalate.

Physical Constituents:

- Total ash: not more than 6%
- Acid insoluble ash: not more than 4%
- Alcohol soluble extract: not less than 2%
- Water soluble extract: not less than 10%
- Volatile oil: not less than 4%.

Chemical Constituents:

Alpha-Pinene, Sabinene, Myrecene, Limonene, Cineole, Cymene, Methyl Heptenone, Linalool, Linalyl acetate, Alpha and Beta Terpineol, Alpha- Terpinyl acetate, Borneol, Neryl acetate, Geraniol, Nerol, Neolidol, Heptacosane, Camphene, Terpinene, Alpha-Humulene.

Pharmacological Activity:

Anti-microbial, Analgesic, Anti-inflammatory, Anti-Fungal, Anti-Spasmodic, hepatoprotective.

Cardamom seeds are widely used for flavouring purposes in food and as carminative. . A comparative study of the anti-inflammatory activity of the oil extracted from commercial *Elettaria cardamomum* seeds, in doses of 175 and 280 microliters/kg

and indomethacin in a dose of 30 mg/kg against acute carrageenan-induced planter oedema in male albino rats was performed, which proved to be marked. Moreover, investigation of the analgesic activity using p-benzoquinone as a chemical stimulus proved that a dose of 233 microliters/kg of the oil produced 50% protection against the writhing (stretching syndrome) induced by intraperitoneal administration of a 0.02% solution of p-benzoquinone in mice (al-Zuhair H etal, 2007)

Substitutes and adulterants:

Amomum subulatum Roxb. as substitute

Other common adulterants are:

- E. cardamomum var. major Thw,
- Amomum kepulaga Sprague and burkill
- Amomum korarima Periera
- Amomum aromaticum Roxb.
- Amomum xanthioides Wallich

கருஞ்சீரகம்

Botanical Name: *Nigella sativa*.Linn

Classical /Vernacular Names: அரணம், உபகுஞ்சிகை

Natural Order: Ranunculaceae

சுவை: கைப்பு

தன்மை: வெப்பம்

பிரிவு: கார்ப்பு

செய்கை: வெப்பமுண்டாக்கி, அகட்டுவாய்வகற்றி, பசித்தீதூண்டி, சிறுநீர்பெருக்கி, ருதுவுண்டாக்கி, பாற்பெருக்கி, புழுக்கொல்லி, வறட்சியகற்றி

குணம்:

கருஞ்சீ ரகத்தான் கரப்பனொடு புண்ணும்

வருஞ்சிராய்ப் பீநசமு மாற்றும்-அருந்தினால்

காய்ச்சல் தலைவலியுங் கண்வலியும் போமுலகில்

வாய்ச்ச மருந்தெனவே வை.

Botanical Description:

Seeds trigonous, black, rugulose-tubercular.

Parts Used: seed, seed oil

Pharmacognosy:

Seeds are small dicotyledonous, trigonous, angular, rugulose-tubercular, black externally and white inside, odour slightly aromatic; taste bitter.

Physical Constituents:

- Total ash: not more than 6%
- Acid insoluble ash: not more than 0.2%
- Alcohol soluble extract: not less than 20%
- Water soluble extract: not less than 15%
- Volatile oil: not less than 0.42%.

Chemical Constituents:

esters of dehydrostearic and linoleic acid, aliphatic alcohol, carvone, d-limonene, cymene, nigellone, alkaloids, stearoids, nigellidine-indazole, alkaloid thymoquinone.

Pharmacological Activity:

Anti-microbial, Analgesic, Anti-inflammatory, Anti-Fungal, Anti-Spasmodic, hepatoprotective, Antipyretic, bronchodilator, galactagogue.

The pharmacological actions of the crude extracts of the seeds (and some of its active constituents, e.g. volatile oil and thymoquinone) that have been reported include protection against nephrotoxicity and hepatotoxicity induced by either disease or chemicals. The seeds/oil have antiinflammatory, analgesic, antipyretic, antimicrobial and antineoplastic activity. The seeds are characterized by a very low degree of toxicity. Administration of either the seed extract or its oil has been shown not to induce significant adverse effects on liver or kidney functions (Ali BH et al, 2003). Thymoquinone, as one of the major components of nigella sativa had potent analgesic and anti-inflammatory property (Hajhashemi V et al, 2004).

திராகைடி

Botanical Name: *Vitis vinifera* Linn

Classical /Vernacular Names: அராவாரம், கொடிமுந்திரிகை, மதுரசம், கோத்திரிகை, திராக்கம், பலோத்தமை

Natural Order: Vitaceae

சுவை: இனிப்பு

தன்மை: தட்பம்

பிரிவு : இனிப்பு

Botanical Description:

Seeds trigonous, black, rugulose-tubercular.

Parts Used: Ripe fruit (dried), leaf, stem, flower

Pharmacognosy:

Mature dried fruit, a berry, is sticky and pulpy, dark brown to black in colour, oblong or oval, sometimes spherical. Odour sweetish and pleasant; taste sweet.

Physical Constituents:

- Total ash: not more than 3%
- Acid insoluble ash: not more than 0.2%
- Alcohol soluble extract: not less than 25%
- Water soluble extract: not less than 70%

Chemical Constituents:

3-monoglucosides of delphinidin, cyaniding, petunidin, peonidin, malvidin, acetyl and coumaryl glycosides, malic acid, tannic acid

Pharmacological Activity:

Antifungal, antiulcer, hepatoprotective, antioxidant, antibacterial, antiherpetic, cardioprotective, antimutagenic.

Vitis vinifera, known as the grapevine, is native to southern Europe and Western Asia. Grape seed and skin contain several active components including flavonoids, polyphenols, anthocyanins, proanthocyanidins, procyanidines, and the stilbene derivative resveratrol. Grape seed extract in particular has been reported to possess a broad spectrum of pharmacological and therapeutic effects such as antioxidative, anti-inflammatory, and antimicrobial activities, as well as having cardioprotective, hepatoprotective, and neuroprotective effects (Nassiri-As M et al, 2009).

அதிமதுரம்

Botanical Name: *Glycyrrhiza glabra Linn*

Classical /Vernacular Names: அராவாரம், கொடிமுந்திரிகை, மதுரசம், கோத்திரிகை, திராக்கம், பலோத்தமை

Natural Order: Fabaceae

சுவை: இனிப்பு

தன்மை: தட்பம்

பிரிவு: : இனிப்பு

Botanical Description:

Hardy herb or undershrub attaining a height upto 2 m.

Parts Used: Root

Pharmacognosy:

Root is yellowish brown, longitudinally wringled externally: odour is faint and characteristic: taste sweetish.

Chemical Constituents:

Glycyrrhizine, prenylated bioaurone, licoargone:

7- acetoxy-2- methyl-isoflavone, glyzaglabrin, quercetin, kaempferol, astragalin, liquiritigenin and isoliquiritigenin.

Pharmacological Activity:

Anti-microbial, antiviral, hypotensive, hepatoprotective, anti-exudative, spasmolytic, antidiuretic, antiulcer, antimutagenic, antipyretic, antioxidant, anti-inflammatory, expectorant.

Glycyrrhizin and liquorice extract of glycyrrhiza glabra showed anti-inflammatory action (Rackova L etal, 2007).

சீரகம்

Botanical Name: *Cuminum cyminum Linn*

Classical /Vernacular Names: அசை, சீரி, உபகும்பீசம், நற்சீரி, துத்தசாம்பலம், பிரத்தி-விகா, பித்தநாசினி, போசனகுடோரி, மேத்தியம்

Natural Order: Umbelliferae

சுவை: கார்ப்பு, இனிப்பு

தன்மை: தட்பம்

பிரிவு: இனிப்பு

செய்கை: வெப்பமுண்டாக்கி, அகட்டுவாய்வகற்றி, பசித்தீதுண்டி, துவர்ப்பி

குணம்:

பித்தமெனு மந்திரியைப் பின்னப் படுத்தியவன்

சத்துருவை யுந்துறந்து சாதித்து-மத்தனெனும்

ராசனையு மீவென்று நண்பைப் பலப்படுத்தி

போசனகு டாரிசெயும் போர்.

- தேரன் வெண்பா

Botanical Description:

The fruit is a lateral fusiform or ovoid achene 4–5 mm long, containing a single seed.

Parts Used: Fruit or seed

Chemical Constituents:

Thymene, carvone, cuminol or cumic aldehyde, cymene cymol, terpene, carvone, α -pinene, limonene, γ -terpinene, linalool, *p*-cymene, cuminaldehyde, limonene, α - and β -pinene, 1,8-cineole, *o*- and *p*-cymene, α - and γ -terpinene, safranal and linalool.

Pharmacological Activity:

Anti-microbial, antioxidant, antidiabetic, immunomodulator, diuretic.

Cuminum cyminum, which was used daily in food had antimicrobial action against fungi or bacteria (Zaman U etal, 2008).

சாஜிரா

Botanical Name: *Carum bulbocastum Koch*

Classical /Vernacular Names: பிளப்புச்சீரகம், சீமைச்சீரகம்

Natural Order: Umbelliferae

சுவை: கார்ப்பு, இனிப்பு

தன்மை: தட்பம்

பிரிவு: இனிப்பு

செய்கை: அகட்டுவாய்வகற்றி, சிறுநீர்பெருக்கி, ருதுவுண்டாக்கி

குணம்:

உடலுக் கழகாம் உறைப்பித்தம் ஏகும்

அடலுறு வாதம் அதமாம்-கடிசேர்

தளயநகைக் கோட்டுமுலைத் தையலே! நாளும்

பிளவுநறுஞ் சீரகத்தைப் பேண்.

Botanical Description:

The fruit is a lateral fusiform or ovoid achene 4–5 mm long, containing a single seed.

Parts Used: Fruit or seed

Chemical Constituents:

Thymene, carvone, cuminol or cumic aldehyde, cymene cymol, terpene, carvone, α -pinene, limonene, γ -terpinene, linalool, *p*-cymene, cuminaldehyde, limonene, α - and β -pinene, 1,8-cineole, *o*- and *p*-cymene, α - and γ -terpinene, safranal and linalool.

Pharmacological Activity:

Anti-microbial, antioxidant, antidiabetic, immunomodulator, diuretic.

A number of EO components has been identified as effective antibacterials, e.g. carvacrol, thymol, eugenol, perillaldehyde, cinnamaldehyde and cinnamic acid (Burt S, 2004).

பறங்கிச்சக்கை

Botanical Name: *Smilax china.Linn*

Classical /Vernacular Names: மதுஸ்மிகம், மதுஸ்மீகி, சீனப்பட்டை, பறங்கிப்பட்டை

Natural Order: Liliaceae

சுவை: இனிப்பு

தன்மை: தட்பம்

பிரிவு: இனிப்பு

செய்கை: உடல்தேற்றி, மேகப்பிணிவிலக்கி, காமம்பெருக்கி, தூய்மையாக்கி

குணம்:

தாகம் பலவாதந் தாதுநட்டம் புண்பிளவை

மேகங் கடிகிரந்தி வீழ்முலந்-தேகமுடன்

குட்டை பகந்தமேற் கொள்வமனம் போம்பறங்கிப்

பட்டையினை யுச்சரித்துப் பார்.

- தேரையர் குணவாகடம்.

Botanical Description:

Rhizome blackish externally, pale coloured or whitish internally, bitter, acrid.

Parts Used: Rhizome

Chemical Constituents:

Kaempferol-7-O-beta-D-glucopyranoside , engeletin , isoengeletin , kaempferol , dihydrokaempferol , dihydrokaempferol-5-O-P-D-glucopyranoside , rutin , kaempferol-5-O-beta-D-glucopyranoside , 3, 5, 4'-trihydroxystibene , vanillic acid , 3, 5-dimethoxy4-O-beta-D-glu-copyranosylcinnamic acid , beta-sitosterol , and beta-daucosterol.

Pharmacological Activity:

Anodyne, anti-inflammatory, digestive, laxative, depurative, aphrodisiac, diuretic, febrifuge and tonic.

4. MATERIALS AND METHODS

Virana Silethumam is one of the frequently encountered problem among young children in India. Hence it was proposed to study about the disease. A Protocol was prepared and submitted before IEC & IAEC meeting, a copy of which was attached as Annexure-I. After obtaining approval from the committee, the study Preclinical & clinical study on Virana Silethumam (Acute Pharyngo tonsillitis) in children and the drug of choice was malli chooranam was carried out in National Institute of Siddha.

The ingredients for preparation of experimental formulation malli chooranam was purchased from a well reputed country shop and raw drugs were authenticated by Herbal botanist. The medicine was prepared in Gunapadam lab of National institute of Siddha after proper purification. The prepared medicine was also authenticated by the concerned Head Of The Dept for its completeness.

Even though the drugs were pure herb safety of *Malli Chooranam* by Acute Toxicity study were done in animal models according to WHO guidelines, 1993. For acute toxicity study mice were used.

After finishing the toxicity studies 40 cases were selected from the OPD & IPD of Kuzhandhai Maruthuvam Department, National Institute of Siddha. They were treated with the trial drug Malli Chooranam and observed for prognosis clinically.

STUDY DESIGN & CONDUCT OF STUDY:

Study Type: An open clinical trial

Study Place: OPD & IPD of Ayothidass pandithar hospital,

National Institute of Siddha , Tambaram sanatorium, Chennai-47.

Study Period: 12 months

Duration of trial drug: 7 days

Population and Sample:

Inclusion criteria:

- Age : 3-12 Years
- Sex : Both male & female children
- Children with symptoms of cough, sore throat, fever with malaise, swollen tonsils, odynophagia and headache.
- Patients whose parents/guardian are willing to sign the informed consent.
- Patients who are willing to attend OPD once in 7 days/admitted in IPD of Ayothidass Pandithar Hospital.
- Patients who are willing to provide blood, urine for lab investigations.

Exclusion criteria:

- Patient with known history of Primary Complex, Diphtheria/whooping Cough, Allergic Rhinitis with Post nasal drip.
- History of congenital heart disease, seizure disorders.
- Other serious illnesses based on Parental information and previous reports

Sample size was 40 patients

STUDY ENROLLMENT & CONDUCT OF THE STUDY:

Patients reporting at the OPD with the clinical symptoms of sore throat, difficulty to swallow, headache, swollen tonsils, fever and signs of diffuse congestion, lymphadenitis, exudates, petechiae , tonsillar hypertrophy were examined clinically for enrolling in the study based on the inclusion and exclusion criteria.

The patients who were enrolled and their parents were informed about the study, trial drug, possible outcomes and the objectives of the study in the language and terms understandable to them.

After ascertaining the patients' willingness, informed consent was obtained in writing from their parents in the consent form (Form II).

Complete clinical history, complaints and duration, examination findings were recorded in the prescribed Proforma (Form –III). Screening Form- I was filled up; Form-IV and Form –V were used for assessment of symptoms & signs and for recording laboratory investigations respectively. Assessment were made on the basis of clinical features.

Specific investigations of ASO, CRP were done in all patients in addition to the routine blood & urine investigations, before and after treatment.

In the OPD, after initial tests and assessment, trial drug *Malli Chooranam* was given once for 7days after which clinical assessment was done and prognosis noted. In cases where there is need for further treatment due to incomplete improvement, medicines were given in the regular OPD of Ayothidasss Pandithar hospital. The patients were observed for up to 14 days.

In IP, the drug was provided each day for 7 days and prognosis noted after clinical assessment done on a daily basis. Laboratory investigation was done before and after the course of the trial. At the end of the treatment, the patients were advised to visit the OPD for another two weeks for follow-up.

ADMINISTRATION OF TRIAL DRUG:

The drug was prepared by adhering to Standard operative procedure as per the protocol. It was dispensed in sealed polythene covers to prevent contamination. Patients were advised to take the trial drug, twice daily with milk in recommended doses (1.5 gms for 3-7 years/2.5 gms for 8-12 years). The patient compliance form was filled accordingly (Form-VII). Appropriate dietary advice (Form-IX) was given according to the patients' perfect understanding. The patients who were defaulters were withdrawn from the trial.

DATA MANAGEMENT:

After enrolling the patient in the study, a separate file for each patient was opened and all forms were filed in the file. The Data recordings were monitored for completion and adverse event.

The following ASSESSMENT FORMS were used for data collection:

FORM I	SCREENING & SELECTION PROFORMA
FORM II	CONSENT FORM
FORM III	HISTORY PROFORMA
FORM IV	CLINICAL ASSESSMENT FORM
FORM V	LABORATORY INVESTIGATION FORM
FORM VI	PATIENT'S INFORMATION SHEET
FORM VII	WITHDRAWAL FORM
FORM VIII	ADVERSE REACTION FORM
FORM IX	DIETARY ADVICE FORM

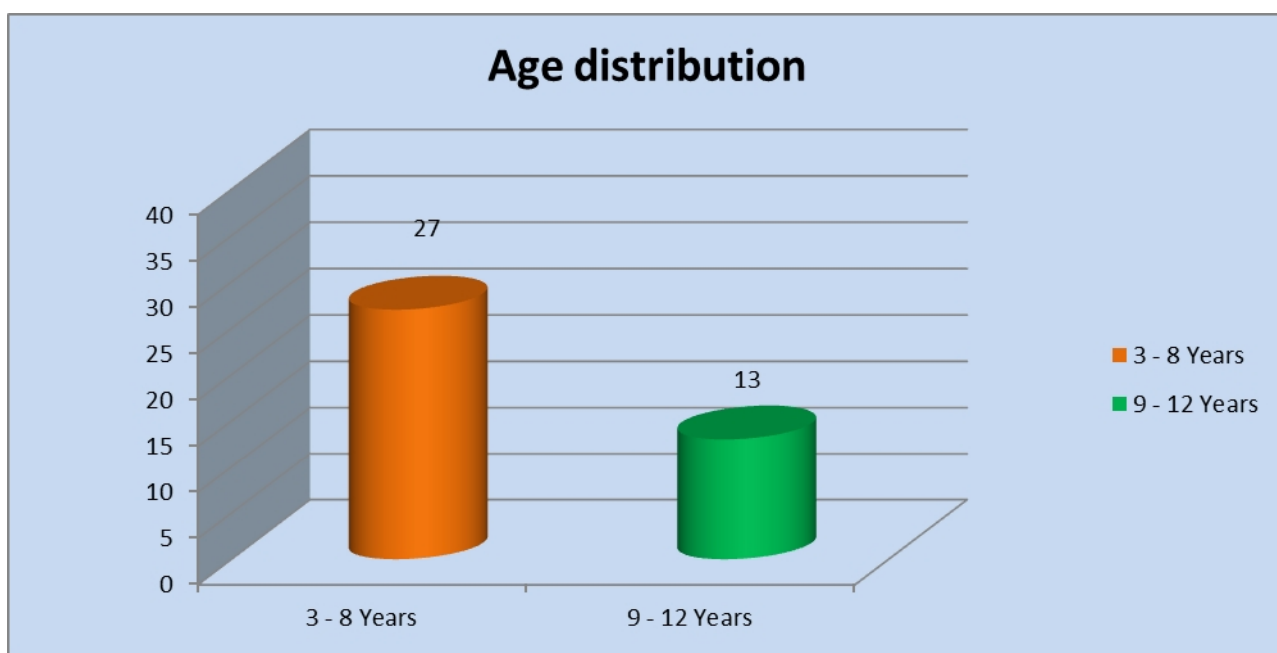
5. RESULTS AND OBSERVATION

For the clinical study, 40 cases were selected and treated in Ayothidoss Pandithar Hospital of National Institute of Siddha, Chennai. Results were observed with respect to the following criteria,

1. Age distribution.
2. Gender distribution
3. Paruvam Distribution
4. Diet Habits
5. Socio – economic status
6. Family history
7. Personal habits
8. Thina reference
9. Seasonal Reference
10. Distribution of three thodam
11. Udal kattugal reference
12. Envagai Thervugal
13. Neerkuri, Neikuri reference
14. Etiological Factors
15. Clinical features
16. Hematological investigation
17. Results after treatment.

AGE DISTRIBUTION:

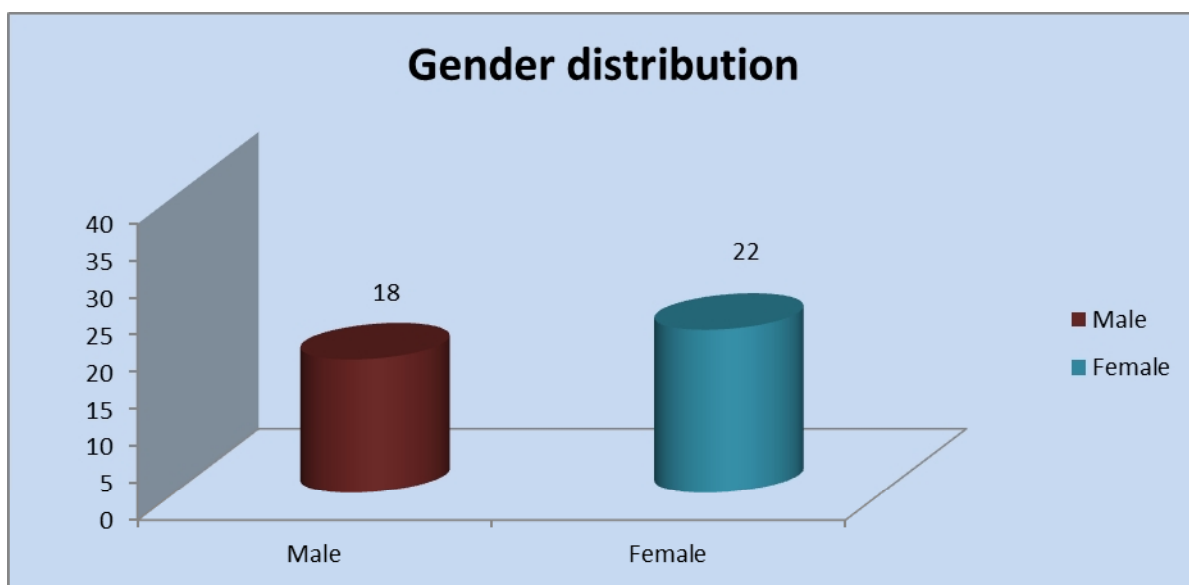
S.No	AGE	No. of Cases	Percentage
1	3 - 8 Years	27	68%
2	9 - 12 Years	13	32%
	Total	40	100%



Out of the 40 cases taken for clinical trial, 27 (68%) cases were in the 3-8 years age group, 13(32%) cases were in the 9-12 years group. The doses of the drugs were given accordingly to these two groups.

GENDER DISTRIBUTION:

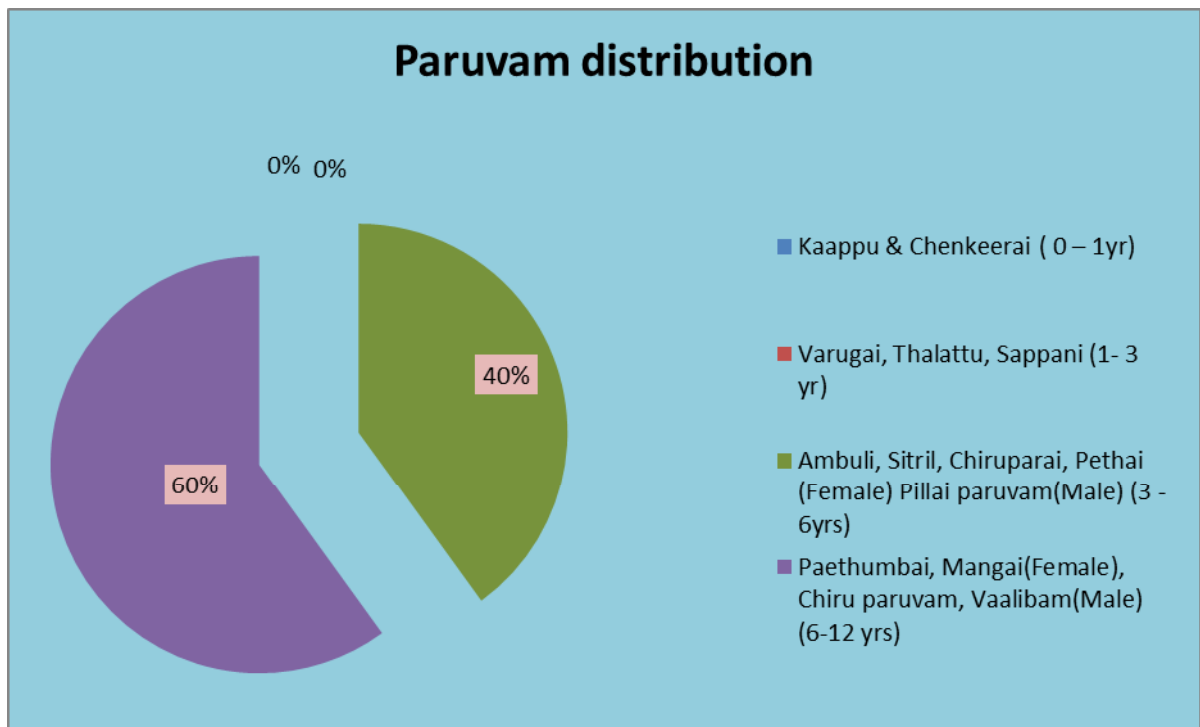
S.No	Sex	No. of Cases	Percentage
1	Male	18	45%
2	Female	22	55%
	Total	40	100%



In the 40 cases treated, 18 (45%) were male and 22 (55%) were female.

PARUVAM DISTRIBUTION:

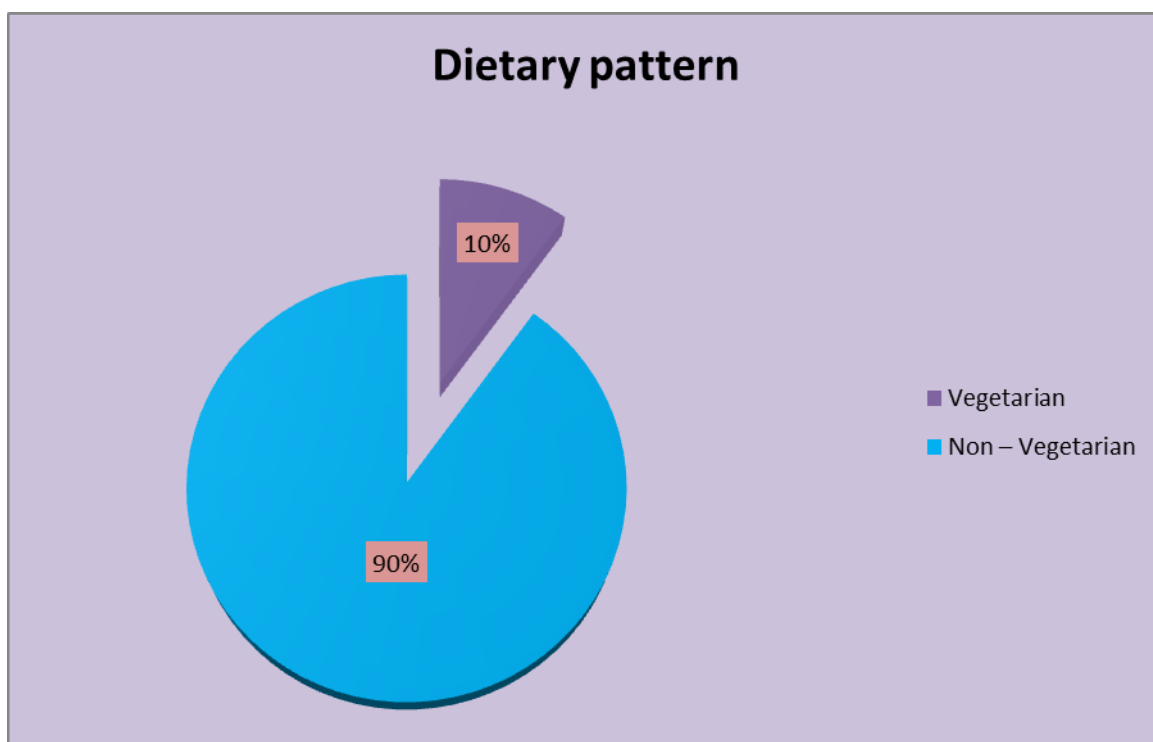
S.No	Paruvam	No. of Cases	Percentage
1	Kaappu & Chenkeerai (0 – 1yr)	-	-
2	Varugai, Thalattu, Sappani (1- 3 yr)	-	-
3	Ambuli, Sitril, Chiruparai, Pethai (Female) Pillai paruvam(Male) (3 -6yrs)	16	40%
4	Paethumbai, Mangai(Female), Chiru paruvam, Vaalibam(Male) (6-12 yrs)	24	60%



In 40 cases, 16 cases were in the 3-6 years age group and 24 were in 6-12 age group.

DIETARY PATTERN:

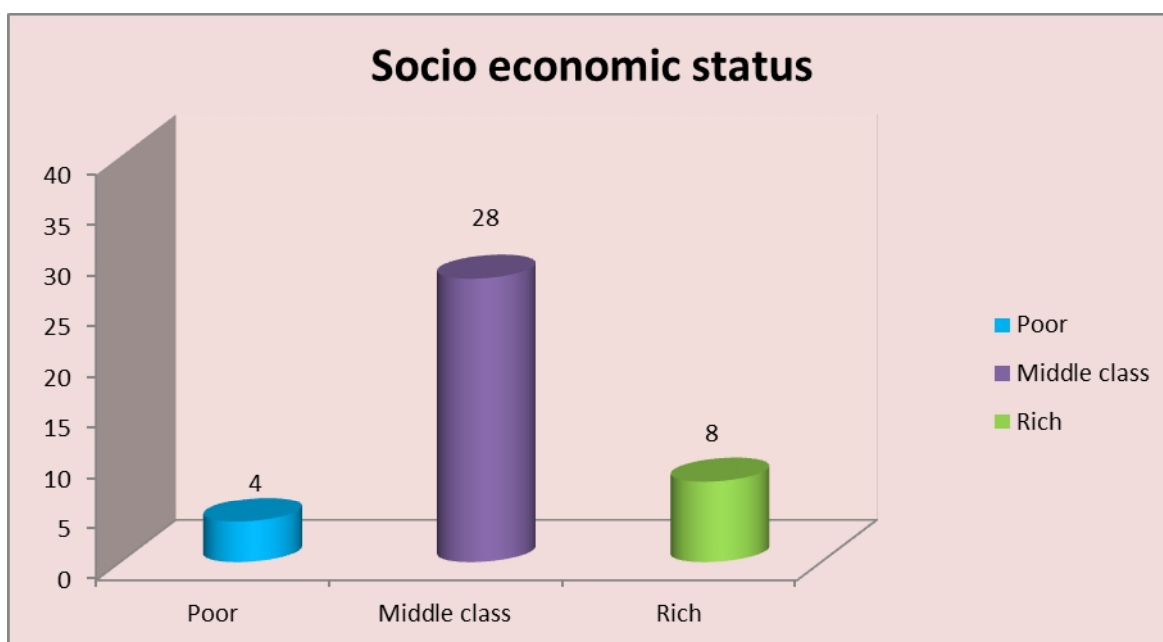
S.No	Diet Habits	No. of Cases	Percentage
1	Vegetarian	5	10%
2	Non – Vegetarian	35	90%
	Total	40	100%



Out of the 40 cases, 5(10%) cases were vegetarians and the rest 35(90%) cases had both vegetarian and non-vegetarian foods for diet.

SOCIO ECONOMIC STATUS

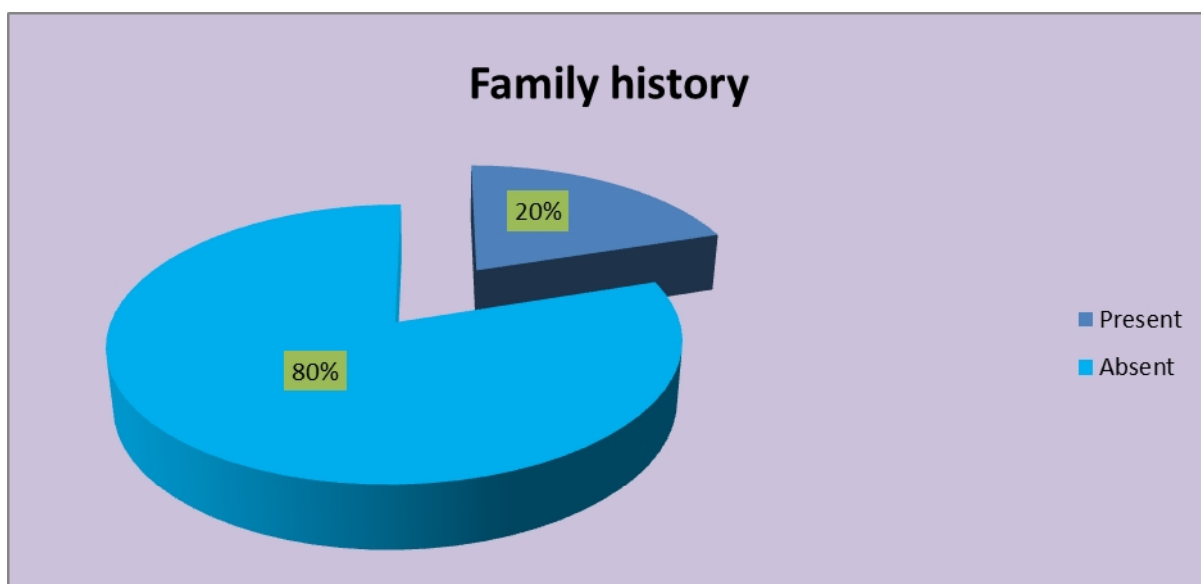
S.No	Economic	No. of Cases	Percentage
1	Poor	4	10%
2	Middle class	28	70%
3	Rich	8	20%
	Total	40	100%



In 40 cases, 4 were from poor, 8 from rich and the remaining 28 from middle income families.

FAMILY HISTORY :

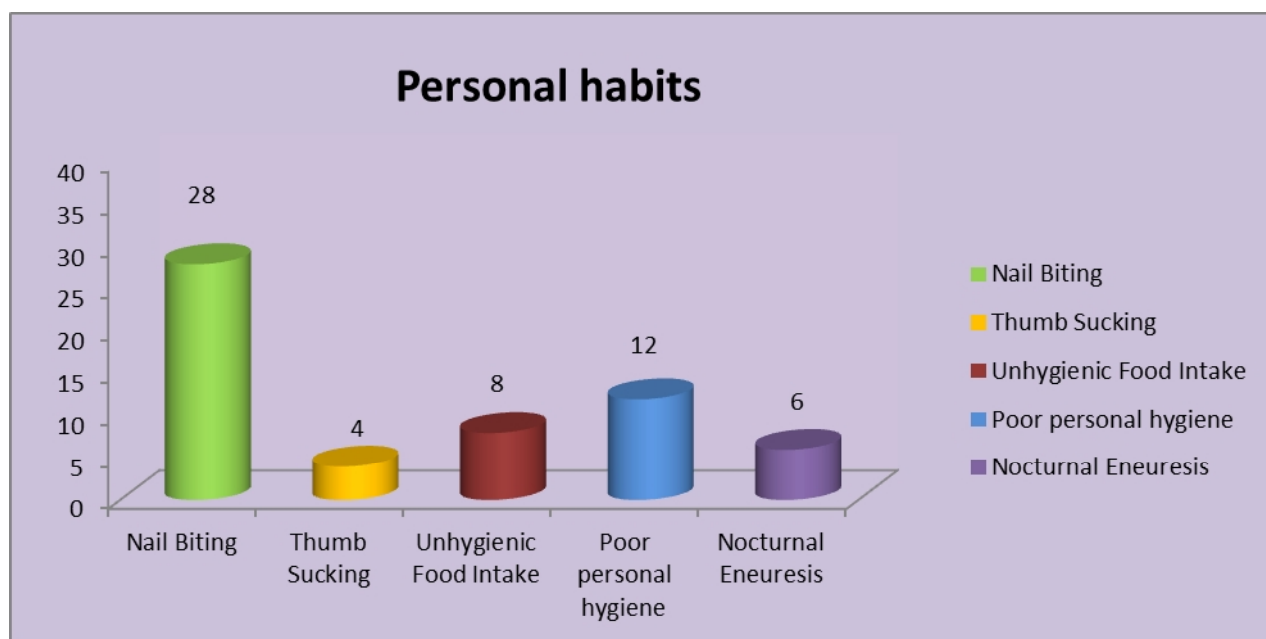
S.No	Family History	No. of Cases	Percentage
1	Present	8	20%
2	Absent	32	80%
	Total	40	100%



Out of the 40 cases, 8 cases (20%) had positive family history and the rest 32 (80%) had no family history or contacts.

PERSONAL HABITS:

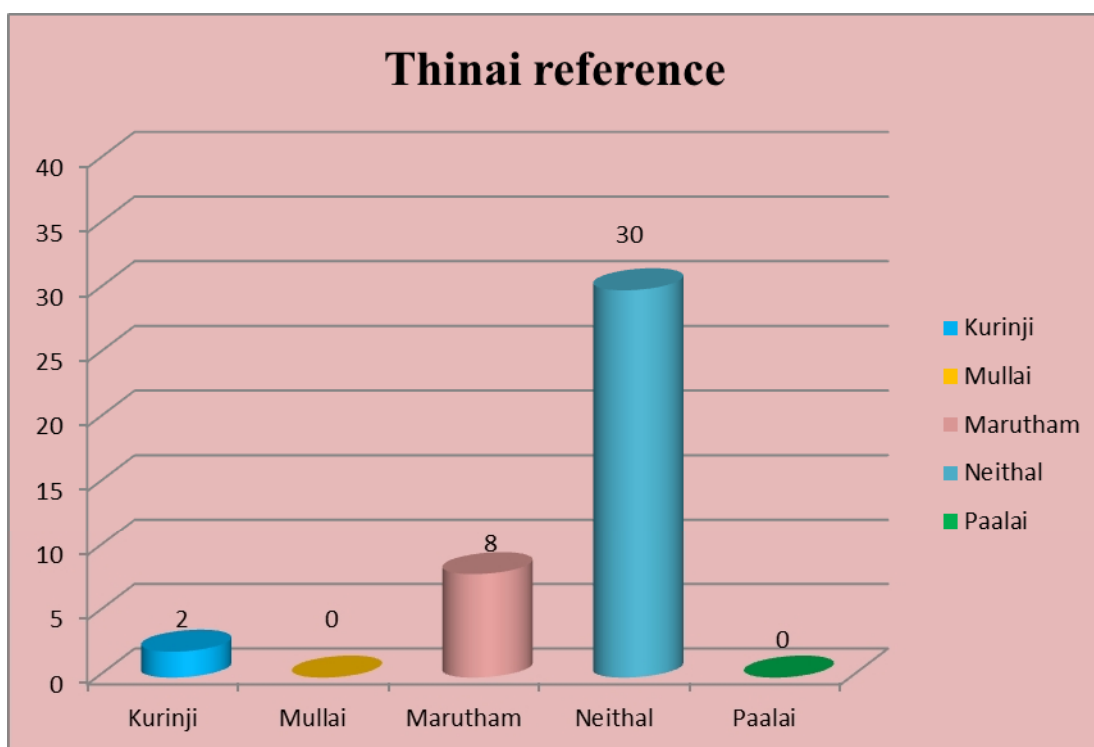
S.No	Personal Habits	No. of Cases	Percentage
1	Nail Biting	28	70%
2	Thumb Sucking	4	10%
3	Unhygienic Food Intake	8	20%
4	Poor personal hygiene	12	30%
5	Nocturnal Eneuresis	6	15%



About 28 (70%) cases in the trial had the habit of nail biting, 12(30%) had poor personal hygiene, 8 (20%) cases had unhygienic food intake in outside eateries, 6(15%) had nocturnal eneuresis.

THINAI REFERENCE:

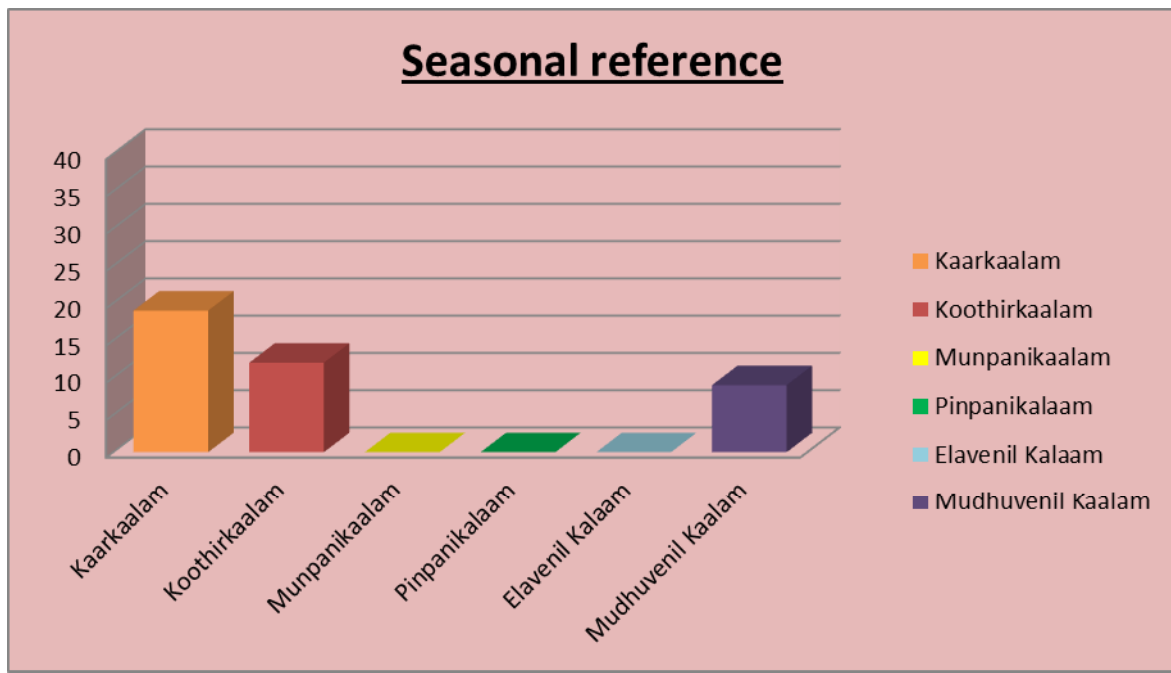
S.No	Thinai History	No. of Cases	Percentage
1	Kurinji	2	5%
2	Mullai	-	-
3	Marutham	8	20%
4	Neithal	30	75%
5	Paalai	-	-
	Total	40	100%



In 40 cases, 30 (75%) cases were from Neithal nilam, 8 (20%) cases were from Marutham nilam and 2 (5%) were from kurinji nilam.

SEASONAL REFERENCE:

S.No	Season	No. of Cases	Percentage
1	Kaarkaalam	19	47.5%
2	Koothirkaalam	12	30%
3	Munpanikaalam	-	-
4	Pinpanikalaam	-	-
5	Elavenil Kalaam	-	-
6	Mudhuvenil Kaalam	9	22.5%
	Total	40	100%

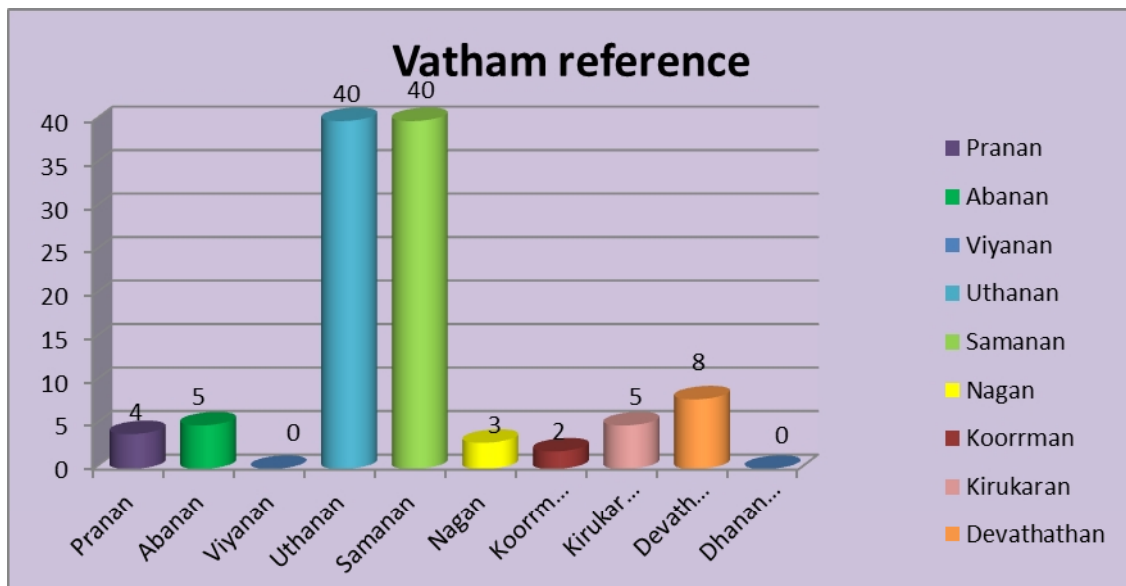


In the trial of 40 cases, majority of about 19(47.5%) cases were registered in kaar kalam, 12(30%) during koothir kalam and 9(22.5%) in muduvenir kalam.

DISTRIBUTION OF THREE THODAM

Table illustrating the derangement of Vatham

S.No	Classification of Vatham	No of cases	Percentage
1	Pranan	4	10%
2	Abanan	5	12.5%
3	Viyanan	-	-
4	Uthanan	40	100%
5	Samanan	40	100%
6	Nagan	3	7.5%
7	Koormman	2	5%
8	Kirukaran	5	12.5%
9	Devathathan	8	20%
10	Dhananjeyan	-	-

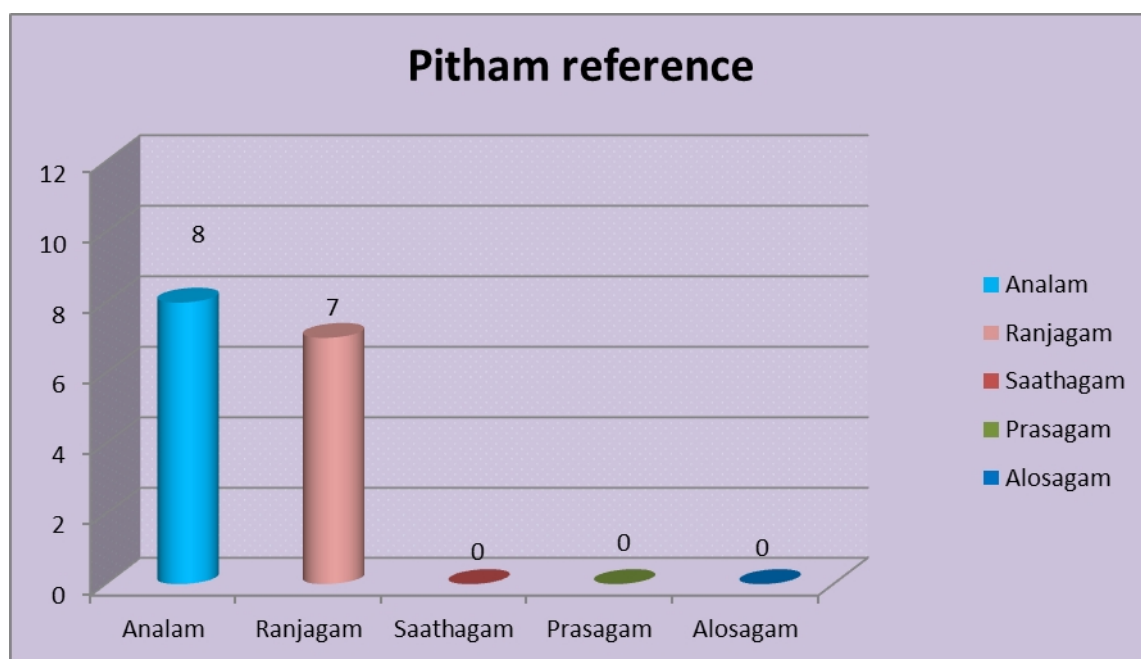


In vatham, uthanan and samanan were affected in all 40 cases.

Devathathan was found to be deranged in 8 cases.

Table illustrating the derangement of Pitham:

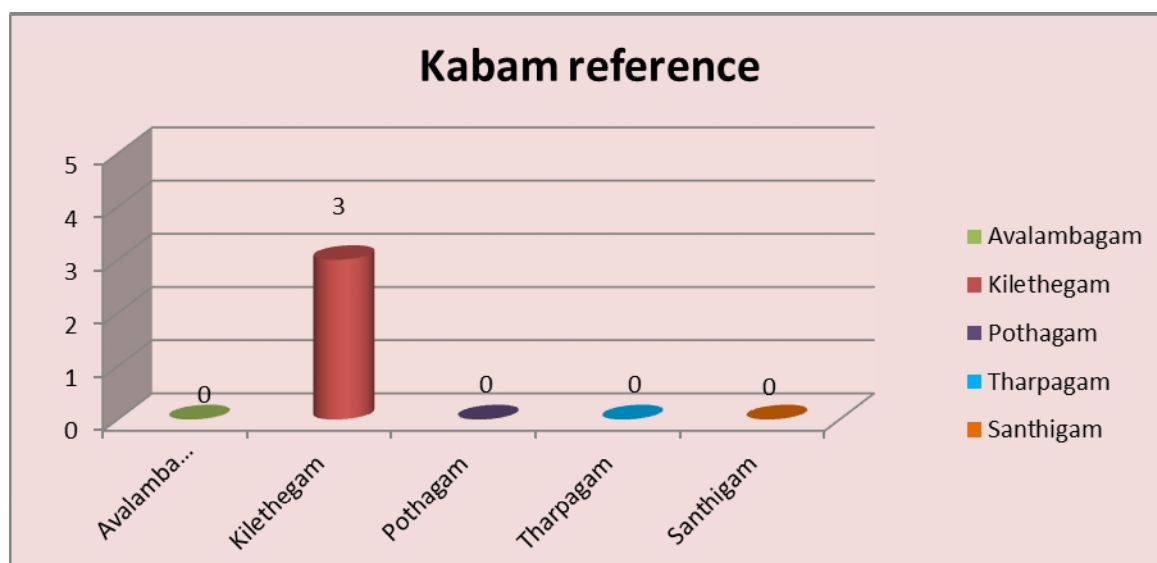
S.No	Classification of Pitham	No of cases	Percentage
1	Analam	8	20%
2	Ranjagam	7	18%
3	Saathagam	0	0%
4	Prasagam	0	0%
5	Alosagam	0	0%



In pitham, ranjagam was found to be affected in 8 (20%) cases and analam in 7 (18%) cases.

Table illustrating the derangement of Kabam:

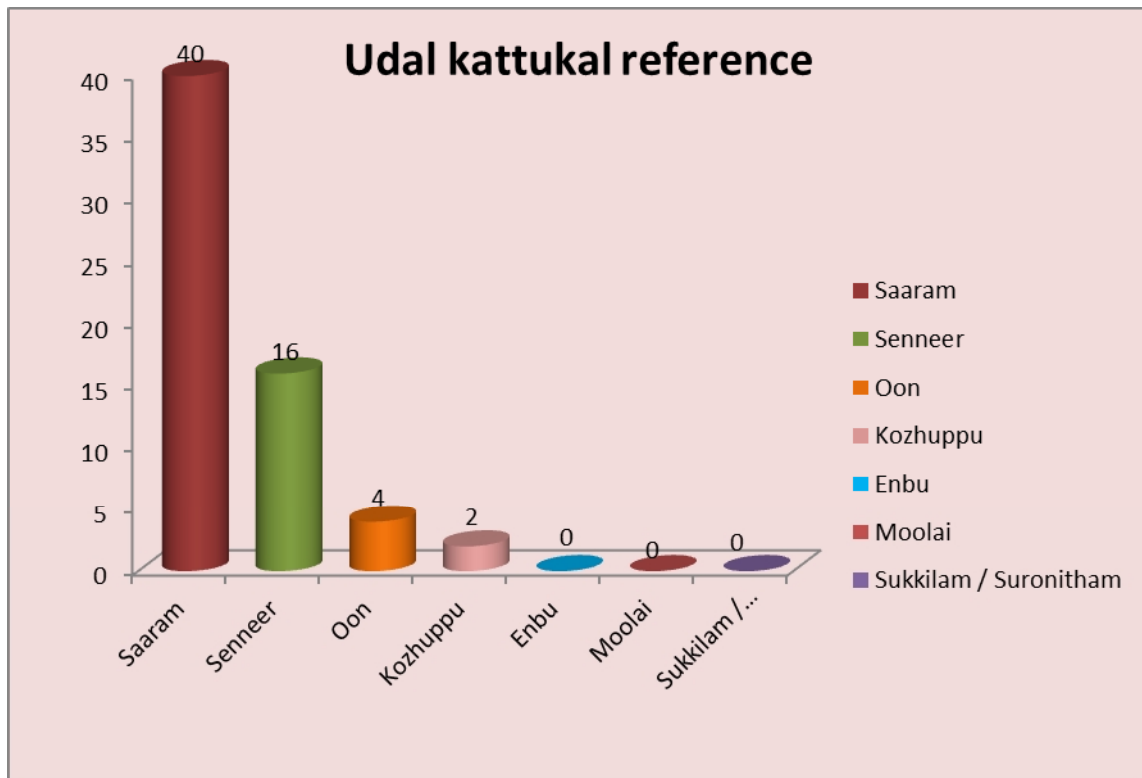
S.No	Classification of Kabam	No of cases	Percentage
1	Avalambagam	-	-
2	Kilethegam	3	8%
3	Pothagam	-	-
4	Tharpagam	-	-
5	Santhigam	-	-



In kabam, only klethagam was affected in 4(10%) cases out of 40 cases.

UDAL KATTUGAL REFERENCE:

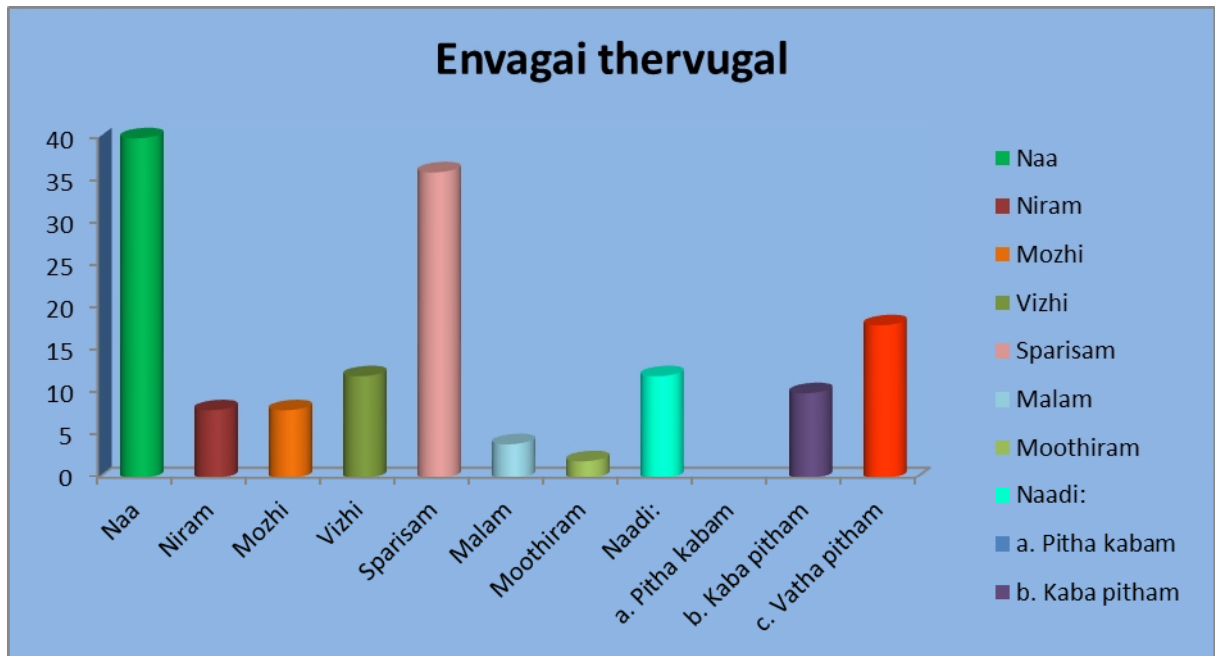
S.No	Types	No of cases	Percentage
1	Saaram	40	100%
2	Senneer	16	40%
3	Oon	4	10%
4	Kozhuppu	2	5%
5	Enbu	0	0%
6	Moolai	0	0%
7	Sukkilam / Suronitham	0	0%



Saaram was affected in all 40 cases, senneer in 16(40%), oon in 4(10%) and kozhuppu in 2 (8%) of the cases.

ENVAGAI THERVUGAL:

S.No	Types	No. of cases	Percentage
1	Naa	40	100%
2	Niram	8	20%
3	Mozhi	8	20%
4	Vizhi	12	30%
5	Sparisam	36	90%
6	Malam	4	10%
7	Moothiram	2	5%
8	Naadi:	12	30%
	a. Pitha kabam	10	25%
	b. Kaba pitham	10	25%
	c. Vatha pitham	18	45%

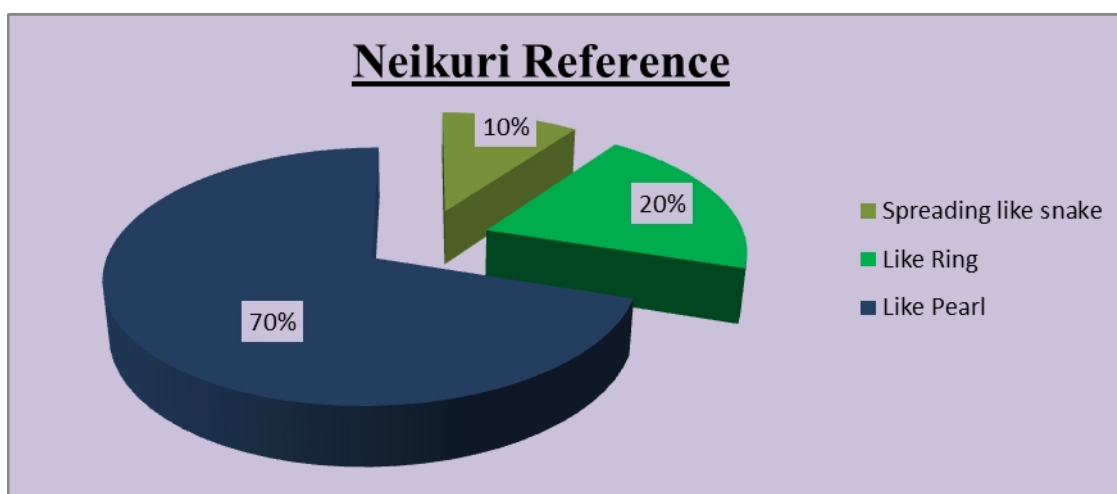
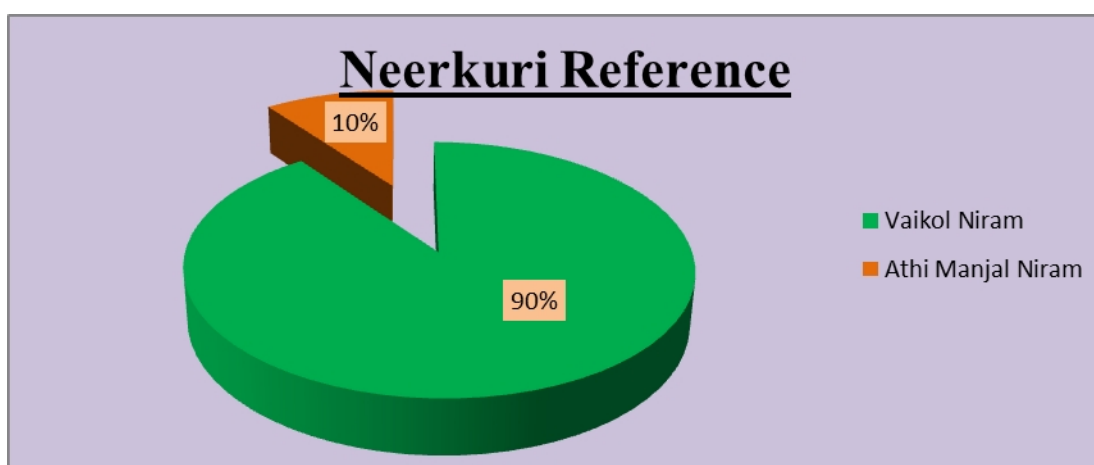


Naa was affected in all 40 cases, vizhi in 12 cases, sparisam in 36 cases, mozhi, niram in 8 case each, malam in 4 cases. Vatha pitham nadi was found in 18 cases.

NEERKURI, NEIKURI REFERENCE:

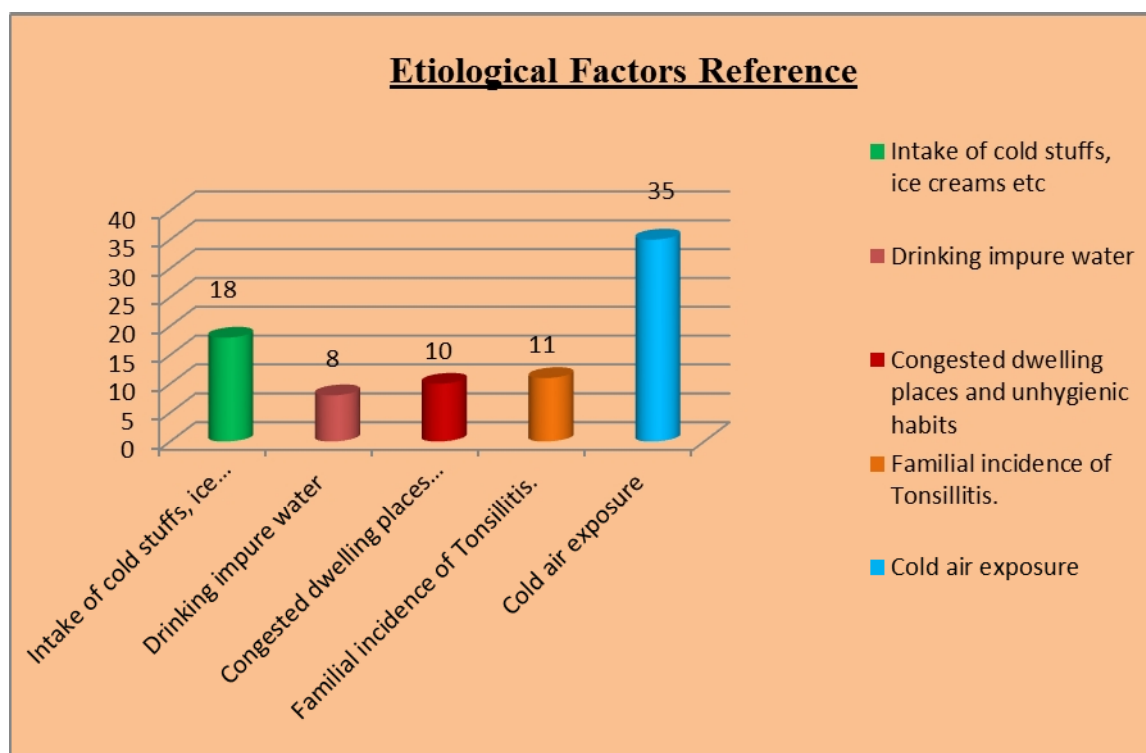
S.No	Types	No of cases	Percentage
1	NEERKURI		
	Vaikol Niram	36	90%
	Athi Manjal Niram	4	10%
2	NEIKURI		
	Spreading like snake	4	10%
	Like Ring	8	20%
	Like Pearl	28	70%

The urine of 36 cases (90%) were in vaikol niram, whereas 4(10%) cases were athi manjal in colour. Kaba neer in 28 cases, pitha neer in 8 & vatha neer in 4 cases.



ETIOLOGICAL FACTORS :

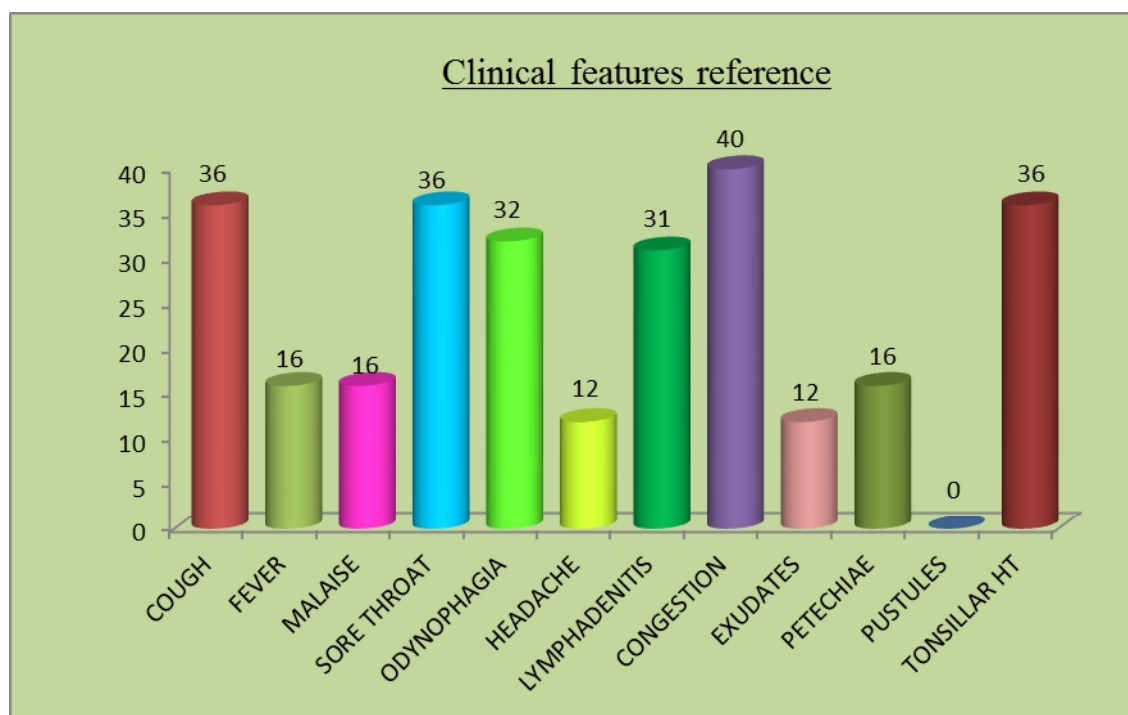
S.No	Etiological factors	No. of Cases	Percentage
1	Intake of cold stuffs, ice creams etc	18	45%
2	Drinking impure water	8	20%
3	Congested dwelling places and unhygienic habits	10	25%
4	Familial incidence of Tonsillitis.	11	28%
5	Cold air exposure	35	88%



In etiological factors, most cases (88%) reported due to cold air exposure followed by intake of cold stuffs which was found in 45% cases.

CLINICAL FEATURES

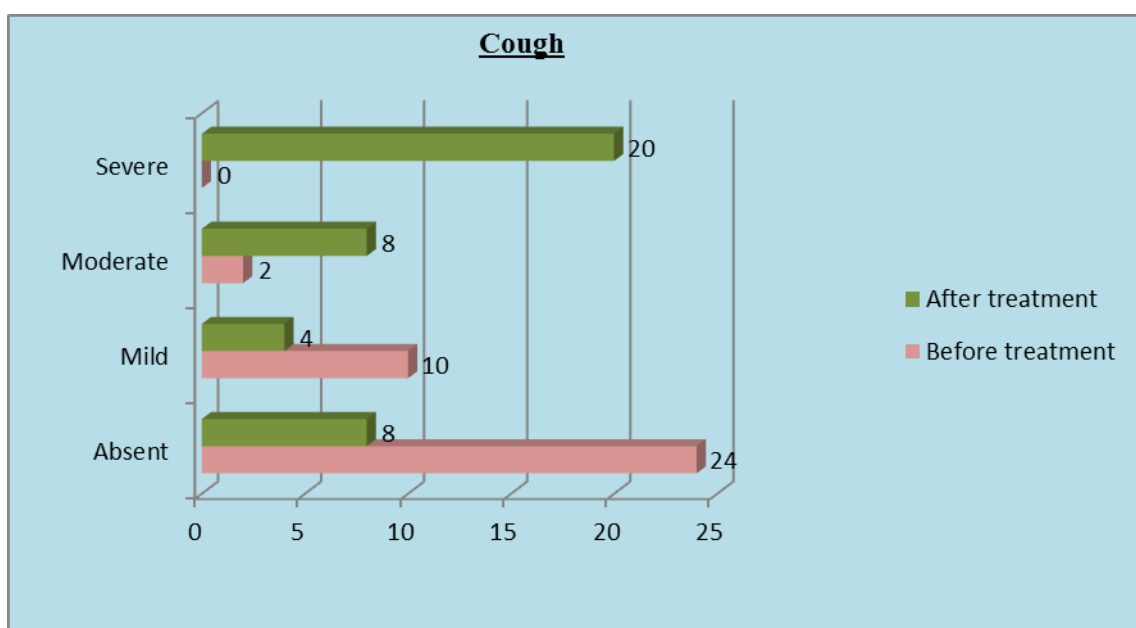
S.No	Clinical features	No of cases	Percentage
1	COUGH	36	90%
2	FEVER	16	40%
3	MALAISE	16	40%
4	SORE THROAT	36	90%
5	ODYNOPHAGIA	32	80%
6	HEADACHE	12	30%
7	ANTERIOR CERVICAL LYMPHADENITIS	31	78%
8	DIFFUSE MUCOSAL CONGESTION	40	100%
9	INFLAMMATORY EXUDATES	12	30%
10	PETECHIAE	16	40%
11	PUSTULES	-	-
12	TONSILLAR HYPERTROPHY	36	90%



Cough was the predominant symptom present in 36 cases out of 40 cases.

COUGH ANALYSIS:

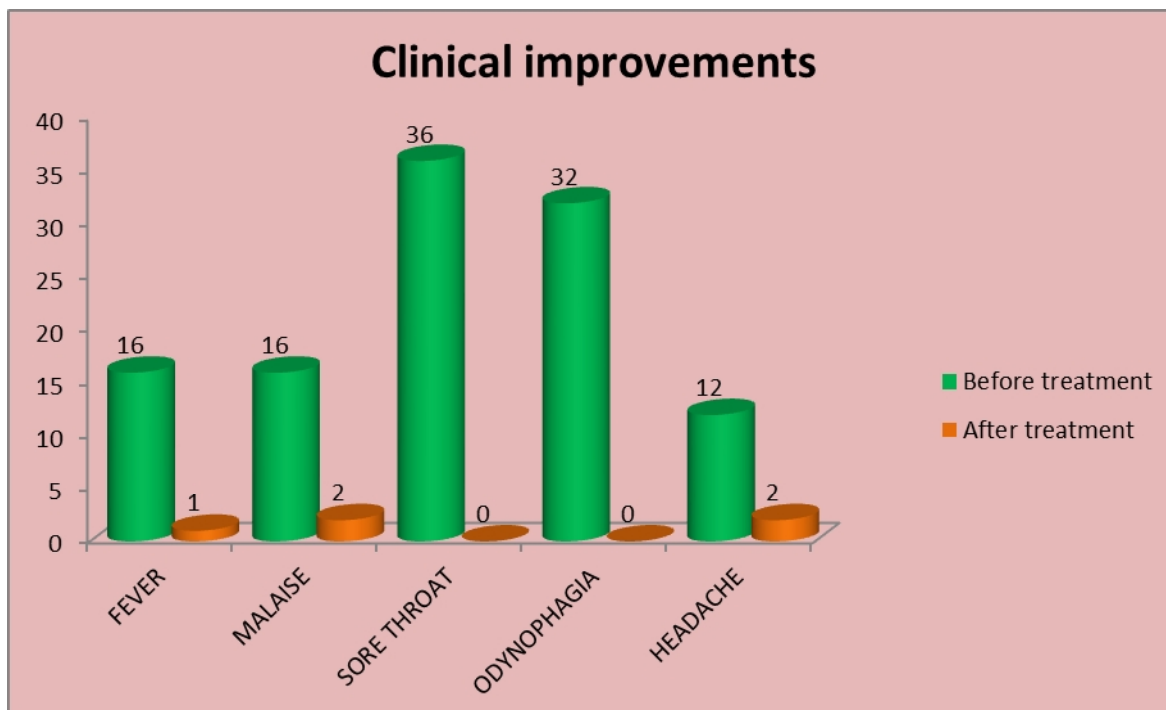
S.No	COUGH	Absent	Mild	Moderate	Severe
1	After Treatment	24	10	2	0
2	Before Treatment	8	4	8	20



The number of cases with severe cough reduced from 20 (before treatment) to 0 (after treatment). The number of cases without cough increased from 8 to 24 after treatment.

DISEASE PROGNOSIS:

S.No	Clinical features	Before Treatment	After Treatment
1	FEVER	16	1
2	MALAISE	16	2
3	SORE THROAT	36	0
4	ODYNOPHAGIA	32	0
5	HEADACHE	12	2

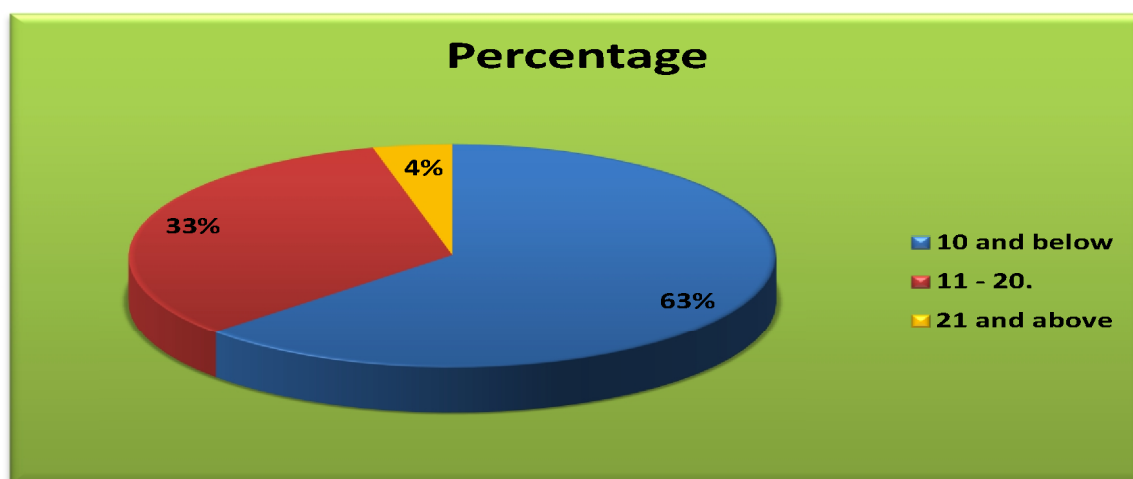


The number of cases relieved of fever was 15 out of 16 & without malaise was 14 out of 16 and headache was 10 out of 12. All cases with sore throat and odynophagia was relieved of their symptoms.

HEMATOLOGICAL INVESTIGATION:

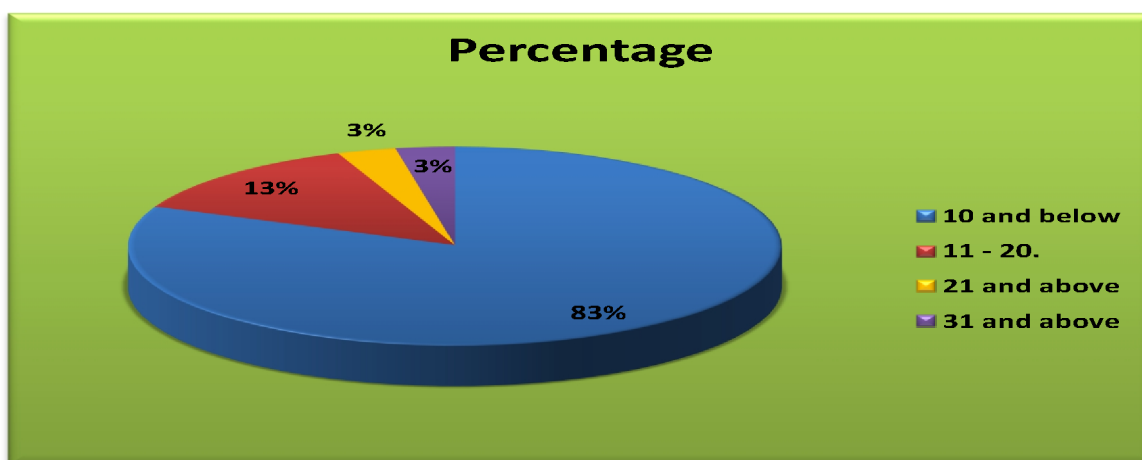
Erythrocyte Sedimentation rate (ESR/ hour) before treatment:

S. No	ESR/hour in mm	No of cases	Percentage
1	10 and below	24	60%
2	11 - 20.	12	30%
3	21 and above	4	10%



Erythrocyte Sedimentation rate (ESR/ hour) after treatment:

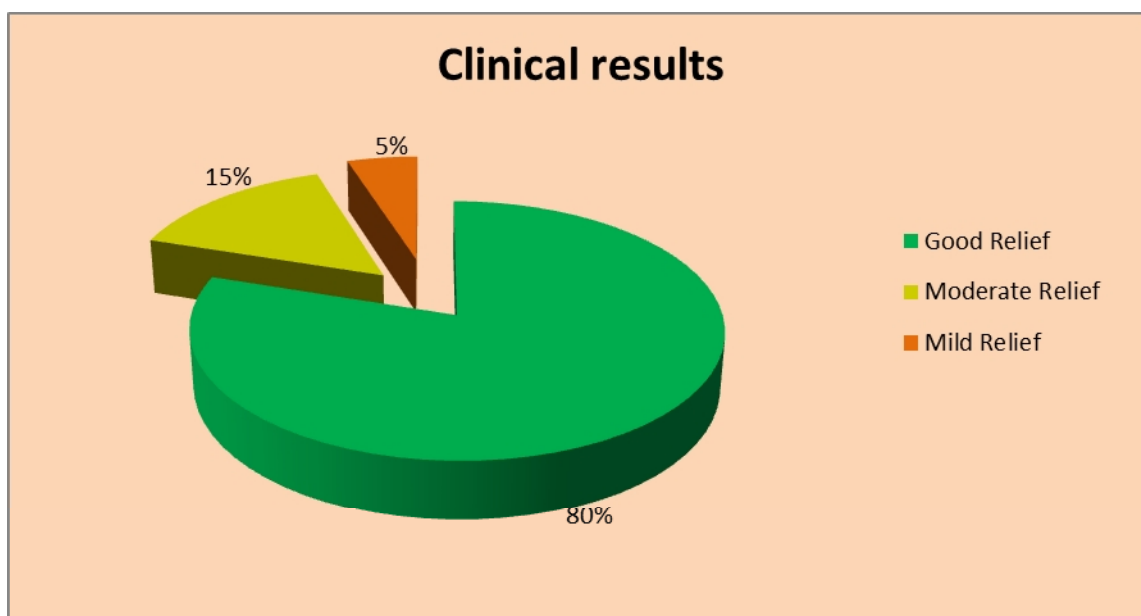
S. No	ESR/hour in mm	No of cases	Percentage
1	10 and below	33	83%
2	11 - 20.	5	13%
3	21 and above	1	3%
4	31 and above	1	3%



There is considerable reduction in groups of higher ESR and increase in groups of lower ESR, this proves the fact there is notable reduction in ESR levels on the whole.

RESULTS AFTER TREATMENT:

S.No	Results	No. of Cases	Percentage
1	Good Relief	32	80%
2	Moderate Relief	6	15%
3	Mild Relief	2	5%



Out of the 40 cases taken for trial, 32 cases showed good relief of the symptomatology, 6 cases showed moderate relief and 2 cases showed mild relief.

Lab Analysis Before & After Treatment

S.NO	OP/IP NO	Name	AGE/ SEX	BEFORE TREATMENT										AFTER TREATMENT																	
				BLOOD										BLOOD																	
				Urine										Urine																	
				Hb	TRBC	TWBC	DC			ESR			ASO	CRP	Alb	Dep	PC	Hb	TRBC	TWBC	DC			ESR			ASO	CRP	Alb	Dep	PC
P	L	E	M	1/2 Hr	1 Hr																										
1	D00197	R.Adhirai	5/F	11.2	4.1	8200	52	44	4	0	2	4	N	N	NIL	2-4	1-2	10.8	3.6	7000	48	47	45	0	8	16	P	N	NIL	2-4	1-2
2	C578	S.Buvarneswari	8/F	12.1	4	6800	61	38	1	0	2	4	N	N	NIL	2-4	1-2	10.4	3.4	7400	53	42	5	0	2	4	N	N	NIL	3-6	2-4
3	A74753	Dhiya	6/F	8.9	2.9	5800	40	59	1	0	4	8	N	N	NIL	1-3	1-3	9.7	3.8	3800	39	60	1	0	4	8	N	N	NIL	1-2	1-2
4	A67920	Manoj Kumar	11/M	8.7	2.9	7400	63	34	3	0	4	8	N	N	NIL	3-5	2-4	10.2	3.6	5600	45	53	2	0	4	8	N	N	NIL	2-4	2-4
5	C812	Loganathan	8/M	9.6	3.2	6000	60	36	4	0	2	4	N	N	NIL	1-3	1-2	10.4	3.5	7500	35	63	2	0	2	4	N	N	NIL	2-4	2-4
6	C813	Kavitha	5/F	9.2	3	7600	55	43	2	0	2	4	N	N	NIL	3-4	1-3	11.2	4.7	8300	58	41	1	0	2	4	N	N	NIL	1-3	1-3
7	B30437	Aruna	8/F	9.6	3.2	5800	69	27	4	0	2	4	N	N	NIL	2-4	2-4	9.6	3.2	7800	63	29	8	0	4	8	N	N	NIL	3-6	3-6
8	A17116	P.Praveen	8/M	9.6	3.2	8200	40	58	2	0	16	32	N	N	NIL	2-4	2-4	9.2	3	7500	49	50	1	0	4	8	P	N	NIL	2-4	2-4
9	B68801	Adithya	5/M	12.4	4.1	11000	50	49	1	0	5	10	N	N	NIL	PLENTY	4-8	10.3	3.6	6600	43	54	3	0	2	4	N	N	NIL	2-4	2-4
10	C10512	G.Harini	10/F	9.6	3.2	7600	58	38	4	0	2	4	N	N	NIL	8-10	8-10	10.6	3.9	6500	46	52	2	0	6	12	N	N	NIL	8-10	8-10
11	B95484	Meena	7/F	8.7	2.9	10000	55	37	8	0	6	12	N	N	NIL	2-4	1-2	9.5	3.6	8600	45	45	10	0	2	4	N	N	NIL	3-4	1-2
12	C11569	Kavitha	6/F	10	3.3	9000	30	69	1	0	8	16	N	N	NIL	2-4	2-4	10.4	3.4	8200	35	61	4	0	2	4	N	N	NIL	2-4	2-4
13	C14461	Nithya	8/F	10.1	3.6	6400	47	48	5	0	2	4	N	N	NIL	2-4	1-2	10.2	3.7	5400	38	55	7	0	2	4	N	N	NIL	4-5	4-5
14	C14752	Priya	4/F	9.1	3.8	4700	34	62	4	0	6	12	N	N	NIL	2-4	2-4	10.1	4.3	6300	60	36	4	0	2	4	N	N	NIL	2-4	1-2
15	B30573	Kumar	5/M	10.4	3.4	8200	48	51	1	0	8	16	N	N	NIL	3-6	3-6	10	3.6	7300	46	51	3	0	2	4	N	N	NIL	2-4	2-4
16	C13458	Vidhya sagar	11/M	9.2	3.4	9900	48	48	4	0	6	12	N	N	NIL	2-4	1-2	9.2	3	7400	74	21	5	0	4	8	N	N	NIL	2-4	2-4
17	B93497	Thiyagu	6/M	8.3	2.7	8500	43	53	4	0	6	12	N	N	NIL	2-4	2-4	9.7	3.2	6600	71	24	5	0	14	28	N	N	NIL	2-4	2-4
18	C17508	R.S.Vineetha	3/F	8.7	2.9	6700	22	65	13	0	2	4	P	N	NIL	1-2	1-2	8.9	3	6800	42	50	8	0	2	4	P	N	NIL	1-2	1-2
19	C14883	Rajitha	10/F	10.7	3.8	5900	48	50	2	0	2	4	N	N	NIL	2-4	2-4	10	3.5	6700	50	42	8	0	6	12	N	N	NIL	4-6	2-4
20	C5628	S.Ruthasree	4/F	10.5	3.8	9300	50	48	2	0	8	16	N	N	NIL	1-2	2-4	9.6	3.2	8500	27	70	3	0	4	8	N	N	NIL	1-2	1-2

Hb- hemoglobin in gm/dl, TRBC- Total RBC count in cells/cmm, Twbc- total wbc count in cells/cmm, DC – Differential Count P-Polymorphs, L-Lymphocyte, E- Eosinophils, M-Monocytes in %, ESR in mm/hr, ASO – Anti Streptolysin O, CRP- C reactive protein, Alb- albumin, EC- epithelial cells, PC- puscells, in Hpf

Lab Analysis Before & After Treatment

S.NO	OP/IP NO	Name	AGE/ SEX	BEFORE TREATMENT										AFTER TREATMENT																	
				BLOOD										BLOOD																	
				Hb	TRBC	TWBC	DC			ESR			ASO	CRP	Alb	Dep		Hb	TRBC	TWBC	DC			ESR		ASO	CRP	Alb	Dep		
							P	L	E	M	1/2 Hr	1 Hr				EC	PC				P	L	E	M	1/2 Hr				1 Hr	EC	PC
21	C15496	Prem Kumar	12/M	11.3	4.4	6200	40	50	10	0	4	8	N	N	NIL	1-2	1-2	11.1	4.4	7700	80	18	2	0	8	16	N	N	NIL	1-2	1-2
22	C13571	Fazila	11/F	11.5	4	7500	50	48	2	0	2	4	N	N	NIL	2-4	2-4	10.8	3.6	6500	62	35	3	0	2	4	N	N	NIL	3-6	3-5
23	C15334	V.J.Amal	11/M	11.7	3.9	11200	56	43	1	0	2	4	N	N	NIL	2-4	2-4	9.6	3.2	6500	38	56	6	0	4	8	N	N	NIL	2-4	1-2
24	B71092	Sweety	6/F	11.1	4.2	4800	50	42	8	0	4	8	N	N	NIL	0-1	1-2	11.5	4.3	8500	63	32	5	0	3	6	N	N	NIL	2-4	2-4
25	A92212	Kalaivani	12/F	10.8	3.6	15000	69	25	6	0	8	16	N	P	NIL	1-2	1-2	10	3.3	7400	57	41	2	0	2	4	N	N	NIL	2-4	2-4
26	A91337	Rajalaksmi	9/F	12.8	4.7	9900	56	36	4	4	2	4	N	N	NIL	3-4	1-2	11.9	4.2	12000	60	36	4	0	2	4	N	N	NIL	1-2	1-2
27	C17611	Susinder	12/M	10	3.3	5800	69	30	1	0	10	20	N	N	NIL	1-2	1-2	9.6	3.2	6700	59	39	2	0	4	8	N	N	NIL	1-2	1-2
28	B61262	Lavanya	12/F	10.8	3.6	7600	76	23	1	0	8	16	P	N	NIL	2-4	2-4	11.2	3.7	6600	55	36	9	0	4	8	P	N	NIL	2-4	1-2
29	B74289	Vaishnavi	4 1/2/F	10	3.3	7000	62	36	2	0	2	4	N	N	NIL	4-5	4-5	10.3	2.8	8000	51	44	5	0	2	4	N	N	NIL	2-4	1-2
30	B53740	Srilekha	8/F	11.1	4.1	7600	46	48	6	0	5	10	N	N	NIL	1-2	1-2	11.2	3.2	7600	57	37	6	0	5	10	N	N	NIL	1-2	1-2
31	B94984	Prabakaran	9/M	10.7	3.8	5300	40	53	7	0	4	8	N	N	NIL	2-4	1-3	10	3.6	6800	43	30	27	0	2	4	N	N	NIL	4-6	2-4
32	B97822	A.Balaji	12/M	10.9	4	6200	45	53	2	0	2	4	N	N	NIL	1-2	1-2	10.7	4.1	6200	46	51	3	0	2	4	N	N	NIL	1-2	2-4
33	AR4362	C.Christy	11/F	8.3	3.1	14,200	84	13	3	0	4	8	N	N	NIL	3-6	2-4	9.1	3.8	12100	67	30	3	0	4	8	N	N	NIL	2-4	3-6
34	799	Anburani	9/F	11.9	3.8	6200	63	34	3	0	5	10	N	N	NIL	2-4	3-6	11.5	3.8	6300	56	41	3	0	4	8	N	N	NIL	1-2	1-2
35	803	Ranjith	12/M	12.2	4.4	5,900	58	41	1	0	2	4	N	N	NIL	3-6	2-4	12.2	4.3	5900	57	42	1	0	16	32	N	N	NIL	2-4	1-2
36	833	Kruba	8/M	12.3	4.4	11,500	60	34	6	0	8	16	P	N	NIL	1-3	2-4	12	4.3	11300	52	44	4	0	4	8	P	N	NIL	1-2	2-4
37	834	Nithin Prakash	4 1/2/M	10.8	5	11,600	40	49	11	0	6	12	N	N	NIL	2-4	2-4	10.8	5.2	10200	45	47	8	0	4	8	N	N	NIL	2-4	1-2
38	858	Angel jowitha.L	6/F	10	3.5	7400	45	49	6	0	14	28	P	N	NIL	1-2	1-2	10.2	3.7	7200	43	55	2	0	8	16	P	N	NIL	1-2	1-2
39	864	Snegha	10/F	9.6	3.4	6100	40	55	5	0	7	14	N	N	NIL	1-2	2-3	9.5	3.6	6300	46	51	3	0	4	8	N	N	NIL	1-2	2-3
40	868	Prithvi	7/M	11.1	4.4	7100	47	50	3	0	4	8	N	P	NIL	2-4	1-2	11.4	4.6	6900	49	49	2	0	2	4	N	P	NIL	2-4	1-3

Hb- hemoglobin in gm/dl, TRBC- Total RBC count in cells/cmm, Twbc- total wbc count in cells/cmm, DC – Differential Count P- Polymorphs, L- Lymphocyte, E- Eosinophils, M-Monocytes in %, ESR in mm/hr,ASO – Anti Streptolysin O, CRP- C reactive protein, , Alb- albumin, , EC- epithelial cells, PC- puscells, in Hpf.

Improvement in Clinical Symptoms of Viranasilethumam before and after treatment:

S.NO	OP/IP NO	Name	AGE/SEX	COUGH		FEVER		MALAISE		SORE THROAT		ODYNOPHAGIA		HEADACHE	
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	D00197	R.Adhirai	5/F	++	-	+	-	+	-	+	-	+	-	-	-
2	C578	S.Buwaneswari	7/M	++	-	-	-	+	-	+	-	-	-	-	-
3	A74753	Dhiya	6/F	+++	-	-	-	-	-	+	-	+	-	-	-
4	A67920	Manoj Kumar	12/F	++	-	-	-	+	-	+	-	+	-	+	-
5	C812	Loganathan	8/M	-	-	-	-	+	-	+	-	+	-	+	-
6	C813	Kavitha	5/F	+++	+	-	-	+	-	-	-	-	-	-	-
7	B30437	Aruna	8/M	++	+	-	-	-	-	+	-	+	-	-	-
8	AI7116	P.Praveen	8/M	-	-	+	-	-	-	+	-	+	-	+	-
9	B68801	Adithya	5/M	+++	++	-	-	-	-	-	-	-	-	-	-
10	C10512	G.Harini	10/F	++	-	-	-	+	-	-	-	-	-	-	-
11	B95484	Meena	7/M	+++	-	-	-	-	-	+	-	+	-	-	-
12	C11569	Kavitha	6/F	+++	-	+	-	+	-	+	-	+	-	-	-
13	C14461	Nithya	8/F	+++	+	-	-	-	-	+	-	-	-	-	-
14	C14752	Priya	5/M	-	-	-	-	-	-	+	-	+	-	-	-
15	B30573	Kumar	5/F	++	-	+	-	-	-	+	-	+	-	-	-
16	C13458	Vidhya sagar	11/M	-	-	-	-	+	-	-	-	-	-	+	-
17	B93497	Thiyagu	6/M	+	-	+	-	-	-	+	-	-	-	-	-
18	C17508	R.S.Vineetha	3/M	-	-	-	-	-	-	+	-	-	-	-	-
19	C14883	Rajitha	11/M	+++	+	-	-	-	-	+	-	+	-	+	-
20	C5628	S.Ruthrasree	4/F	+++	-	-	-	-	-	+	-	+	-	-	-
21	C15496	Prem Kumar	12/M	+++	++	-	-	-	-	-	-	-	-	-	-
22	C13571	Fazila	11/F	++	-	-	-	-	-	+	-	+	-	-	-
23	C15334	V.J.Amal	11/M	++	+	-	-	-	-	-	-	-	-	-	-
24	B71092	Sweety	6/F	-	-	-	-	-	-	+	-	+	-	-	-
25	A92212	Kalaivani	12/F	++	-	+	-	-	-	+	-	+	-	+	-
26	A91337	Rajalaksmi	9/F	-	-	-	-	-	-	+	-	+	-	+	-
27	C17611	Susinder	12/M	+	-	+	-	-	-	-	-	-	-	-	-
28	B61262	Lavanya	12/F	+++	+	-	-	-	-	-	-	-	-	-	-
29	B74289	Vaishnavi	4 1/2/F	+++	+	-	-	-	-	-	-	+	-	-	-
30	B53740	Srilekha	8/F	+++	-	-	-	-	-	+	-	-	-	-	-
31	B94984	Prabaharan	9/M	+++	+	+	-	-	-	+	-	+	-	-	-
32	B97822	A.Balaji	12/M	-	-	-	-	-	-	+	-	-	-	-	-
33	AR4362	C.Christy	11/F	+++	+	+	-	+	-	+	-	+	-	-	-
34	799	Anburani	9/F	+++	+	+	-	+	-	+	-	+	-	+	+
35	803	Ranjith	12/M	++	+	-	-	+	-	+	-	+	-	+	-
36	833	Kiruba	8/M	+++	+	+	-	+	-	+	-	+	-	-	-
37	834	Nithin Prakash	4 1/2/M	+++	+	+	-	+	-	+	-	+	-	+	-
38	858	Angel jovitha.L	6/F	+++	-	+	-	+	-	+	-	+	-	-	-
39	864	Snegha	10/F	+++	+	+	+	+	-	+	-	+	-	-	-
40	868	Prithivi	7/M	++	+	+	-	+	-	+	-	+	-	-	-

Improvement in Clinical Symptoms of Viranasilethumam before and after treatment:

S.NO	OP/IP NO	Name	AGE/SEX	LYMPHADENITIS		CONGESTION		EXUDATES		PETECHIAE		PUSTULES		TONSILLAR HT	
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	D00197	R.Adhirai	5/F	+++	+	+++	+	-	-	-	-	-	-	++	+
2	C578	S.Buwaneswari	7/M	+	-	+++	+	-	-	-	-	-	-	+	+
3	A74753	Dhiya	6/F	+	+	+++	+	-	-	-	-	-	-	++	+
4	A67920	Manoj Kumar	12/F	++	+	+++	+	-	-	-	-	-	-	+	+
5	C812	Loganathan	8/M	+++	+	+++	++	+	-	-	-	-	-	+++	+++
6	C813	Kavitha	5/F	++	+	+++	+	-	-	-	-	-	-	++	++
7	B30437	Aruna	8/M	+	+	++	+	-	-	-	-	-	-	+	+
8	A17116	P.Praveen	8/M	+++	++	+++	+	+	-	+	-	-	-	++	++
9	B68801	Adithya	5/M	++	++	+++	-	+	-	-	-	-	-	+++	+++
10	C10512	G.Harini	10/F	++	+	+++	-	-	-	-	-	-	-	++	+
11	B95484	Meena	7/M	+++	+	+++	+	+	-	+	-	-	-	++	+
12	C11569	Kavitha	6/F	++	+	+++	+	+	-	+	-	-	-	+	-
13	C14461	Nithya	8/F	+++	+	+++	+	-	-	-	-	-	-	+	+
14	C14752	Priya	5/M	-	-	+++	+	+	-	-	-	-	-	+++	++
15	B30573	Kumar	5/F	++	-	+++	-	-	-	-	-	-	-	++	+
16	C13458	Vidhya sagar	11/M	++	-	+++	-	-	-	-	-	-	-	+	-
17	B93497	Thiyagu	6/M	-	-	+++	+	-	-	+	-	-	-	+	-
18	C17508	R.S.Vineetha	3/M	++	+	+++	+	-	-	-	-	-	-	++	++
19	C14883	Rajitha	11/M	++	+	+++	+	-	-	-	-	-	-	+	+
20	C5628	S.Ruthrasree	4/F	+++	+	+++	-	-	-	-	-	-	-	++	+
21	C15496	Prem Kumar	12/M	++	+	+++	++	+	-	-	-	-	-	++	++
22	C13571	Fazila	11/F	-	-	+++	+	+	-	+	-	-	-	++	++
23	C15334	V.J.Amal	11/M	+	+	+++	+	+	+	-	-	-	-	++	++
24	B71092	Sweety	6/F	++	-	+++	-	-	-	-	-	-	-	+	-
25	A92212	Kalaivani	12/F	+	+	+++	++	+	-	-	-	-	-	+	+
26	A91337	Rajalaksmi	9/F	-	-	+++	++	-	-	-	-	-	-	+++	+++
27	C17611	Susinder	12/M	++	+	+++	+	-	-	-	-	-	-	++	+
28	B61262	Lavanya	12/F	++	-	+++	-	+	-	+	-	-	-	++	++
29	B74289	Vaishnavi	4 1/2/F	++	+	+++	-	+	-	+	-	-	-	+++	+++
30	B53740	Srilekha	8/F	++	+	+++	+	-	-	-	-	-	-	+	-
31	B94984	Prabaharan	9/M	-	-	+++	+	-	-	-	-	-	-	+	-
32	B97822	A.Balaji	12/M	-	-	+++	+	-	-	-	-	-	-	++	++
33	AR4362	C.Christy	11/F	+++	+	+++	+	-	-	-	-	-	-	+	-
34	799	Anburani	9/F	-	-	+++	++	+	-	-	-	-	-	+++	+++
35	803	Ranjith	12/M	-	-	+++	-	+	-	+	-	-	-	++	+
36	833	Kiruba	8/M	+++	++	+++	++	+	-	-	-	-	-	++	++
37	834	Nithin Prakash	4 1/2/M	+++	+	+++	+	-	-	-	-	-	-	+	-
38	858	Angel jovitha.L	6/F	-	-	+++	+	-	-	-	-	-	-	++	++
39	864	Snegha	10/F	+	-	+++	+	+	-	-	-	-	-	++	+
40	868	Prithivi	7/M	+	-	+++	-	+	-	-	-	-	-	+	-

6. DISCUSSION

Virana silethumam is one of the recurrent upper respiratory tract infections seen in children due to deranged silethumam. It more or less correlates with acute Pharyngo-tonsillitis. The management for this disease in conventional therapy is using antibiotics or surgical procedure like tonsillectomy. Both have demerits. Hence a herbal formulation malli chooranam is taken for the study in the management of Virana silethumam.

Most of the ingredients of malli chooranam have hot, dry thanmai & kaarpu vibagam which act on deranged silethumam. Also demulcent property of the drug ingredients acting on the vitiated Pitham.

Scientifically many drug ingredient of malli chooranam have antibacterial activity. Most cause for this disease in young children is bacteria. Some drugs have antiinflammayory, analgesic, antipyretic, antioxidant properties. All these properties are beneficial for treating the illness.

Eventhough the trial drug was purely herbal origin for safety toxicity studies were done. No toxicity effect was found in the preclinical study. And also there were no adverse drug effects among trial subjects reported during or after clinical trial.

In the study 40 cases showing clinical features of Virana silethumam were admitted to trial based on the inclusion criteria. History-taking, Clinical assessment, investigations, diagnosis were done based on Siddha and modern literatures. The available data was entered into individual case proforma. The patients were treated with Malli chooranam and recommended dietary pattern. Clinical observations were made on 8th and 14th day of trial.

From the results and observations dealt in previous chapters, clinical discussions are made out.

A slight dominance (68%) in the age group of 3-8 years was observed in the study which is in accordance with the author of Pediatric otolaryngology, John Evans. In the study with 90% enrolled being non-vegetarians literature quotes excessive eating & frequent intake of sour, sweet, pungent foods as causes of excessive phlegm formation. Though over crowding, poor sanitation & malnutrition are predisposing factors only 28% of the subjects were from poor strata.

70% of the cases had nail biting and 30% did not have the habit of washing hands before eating, 20% eating unhygienic foods all predisposing to infections.

Literature states, pearl like static type of Neikuri in kaba illnesses; in the study, around 70% of the cases showed kaba neer. In line with the etiology quote in siddha texts, cold air exposure was found to be the etiology in 88% of the cases which was followed by intake of cold stuffs in 45% cases.

With reference to three thodams,

In vatham: uthanan & samanana were affected in all cases, devedhathan in 20% cases, abanan in 13% cases, and 14% showed deranged kirukaran. Nagan in 8% & koorman was affected in 5% cases each.

In pitham: ranjagam was affected in 18% cases, analam in 20% cases.

In kabam: klethagam was found to be affected in 8% cases.

The clinical features of Virana silethumam correlate with the general clinical manifestations of Acute Pharyngo-tonsillitis.

In accordance with the Clinical manifestations of Virana silethumam, sorethroat was found in 90% cases, lymphadenitis accompanied with fever was present in 78% of cases, cough was the major symptom in 90% cases, difficulty in swallowing due to throat ulcer was present in 80% cases. These cases were diagnosed to have Acute Pharyngo-tonsillitis according to modern parameters.

Regarding the symptoms,

- 24 Cases were completely relieved of cough after treatment, irrespective of the severity with which they first reported. 20 cases with severe cough and expectoration before treatment had only occasional dry cough at the end of treatment.
- 16 Cases reported with fever (either intermittent or continuous), out of which 15 cases were relieved of fever at the end of course.
- 16 Cases with malaise showed improvement.
- 36 Cases with sore throat and 32 cases with odynophagia were relieved of their symptoms at the end of treatment.

- All 12 Cases except two were relieved of their headache.

Regarding the signs,

- Exudates in 12 cases and petechiae in 16 cases were absent at the end of trial.
- In 40 cases with diffuse congestion, 10 cases showed no congestion, 6 cases with moderate & 24 cases was with mild congestion at the end of treatment.
- During the trial, 9 cases showed severe lymphadenitis, 15 with moderate , 7 with mild lymphadenitis. At the end of the trial, 3 cases showed moderate & 21 cases with mild lymphadenitis. 16 cases had no lymphadenitis as against the earlier 9 cases before treatment.
- Reduction in tonsillar hypertrophy was not achieved to greater extent as expected. 1 case showed reduction in G_3 to G_2 ., 6 cases showed reduction from G_2 to G_1 , 9 cases showed reduction in G_1 to G_0 . Significant reduction in tonsillar size was observed only during the earlier stages such as G_1 & G_2 but not in later stages such as G_3 .
- There was significant reduction in ESR in about 19 cases.

In addition, patient reported improvement in other symptoms such as constipation, stomach ache, rhinitis. Irritability and sleeplessness was relieved in younger children. The subjects' appetite and regular bowel movements showed improvement at the end of trial. The drug improves appetite, general sleep, and controls progression of URTI to LRTI.

On basis of Siddha & Modern reasoning, improvement in the clinical features in trial subjects may be due to

- Hot, dry *thanmai* & *kaarpu vibagam* of the drug ingredients acting on the deranged Silethumam.
- Demulcent property of the drug ingredients acting on the vitiated Pitham.
- Anti-microbial activity of the *Eugenol* in the drug is effective against 25 genera of bacteria and virus.
- Significant anti-inflammatory, analgesic, anti-pyretic actions of the drug.

7. SUMMARY

The aim of the study is to study the efficacy of Malli chooranam for the management of virana silethumam with reduction of clinical symptoms. The Siddhars with their tremendous foreseeing and unfathomable knowledge have clearly mentioned the symptomatology, etiology and treatment of Virana silethumam.

The acute toxicity study confirmed the safety of the drug and dosing among pediatric population.

For the clinical study, 40 cases were selected from Department of Kuzhanthai maruthuvam of Ayothidass Pandithar Hospital of National Institute of Siddha, Chennai. Clinical diagnosis was done by means of Siddha and Modern Methodology.

The trial subjects were treated with Malli chooranam twice daily according to the age group. Based on the reporting patients, the improvement in the condition of the patients was observed from the second day itself. Within 4 days, patient showed good relief in symptoms. Observations made during the clinical study showed that the trial drug was clinically effective.

Clinically, Malli chooranam had significant analgesic, anti-pyretic and anti-inflammatory action enough to produce clinical effects.

In clinical observation, it was found that 80% of the patients showed good relief in signs and symptoms. Further, there was no development of any adverse drug reactions in the pediatric population.

8. CONCLUSION

Clinical trial with Malli chooranam showed remarkably good results in the management of Virana silethumam without producing any adverse drug effects.

A safe herbal formulation that can be which is clinically efficacious in treating even acute inflamed conditions like acute pharyngo - tonsillitis. The drug can be safely administered to small infants in the event of recurrent episodes due to climatic changes..

Thus, it is concluded that in a developing countries like ours, the treatment with Malli chooranam will be safe, efficacious and easily available with cost effective ingredients for the welfare of pediatric population.

ANNEXURE-I

PROTOCOL

TITLE:

Preclinical & clinical study on “**VIRANA SILETHUMAM**”(Acute Pharyngo tonsillitis) in children and the drug of choice is MALLI CHOORANAM.

BACKGROUND:

Siddha, one of the oldest Indian Systems of Medicine aims at providing wholesome cure to all ailments a man is deposited with. It is very potent & unique when compared with other traditional systems in existence. In siddha system diseases are classified into 4448 types on basis of the three humours ie, Vatham(wind), Pitham(fire), Kabam(phlegm) constituting the fundamentals of this system. According to Classical Siddha literatures derangement of kabam can lead to 20 different types of diseases, of which Virana silethumam is one of them.

The clinical picture of virana silethumam includes sore throat with mucous and pustular exudates, swelling of anterior and posterior cervical area with fever, rigor, burning sensation all over the body, cough, crying out of severity, ulceration of throat and tongue. The symptomatology of Virana silethumam is grossly comparable with that of Acute Pharyngo-tonsillitis.

Acute Pharyngo-tonsillitis caused by Streptococcus species typically occurs in children aged 5-15 years (Chobby et al, Mar 2009). Around the world sore throat is one of the very common recurrent illnesses in children of which 37% being diagnosed as bacterial acute Pharyngo-tonsillitis.

Antibiotics kill healthy intestinal bacteria which helps to keep the immune system healthy. Also administration of antibiotics and analgesics to children may result in the development of higher resistance (*Arora et al,1999*), recurrences, Reye's syndrome, etc.,. To avoid the unwanted administration of antibiotics in children which may cause many adverse effects I wish to conduct a detailed study about virana silethumam through malli chooranam, a herbal formulation .

The study drug has essential oil containing predominantly derivatives of Eugenol (*Hattori et al 1986*), which act potently against 25 genera of bacteria (including *Streptococcus*, *B.subtilis*) involved in causing pharyngo tonsillitis (*Ghelardini et al 2007*). The drugs *Coriandrum sativum*, *Cuminum cyminum*, *Nigella sativa* possess antibacterial activity. *Glycyrrhiza glabra* possesses anti-inflammatory and anti-allergic activity.

AIM & OBJECTIVES:

Primary objective:

- To evaluate the reduction of clinical symptoms.

Secondary objective:

- To evaluate the Safety of ***Malli Chooranam*** in the treatment of Virana silethumam (Acute Pharyngo-Tonsillitis) through Acute and Sub acute Toxicity in animal models.
- To evaluate siddha co-factors in the course of treatment.
- To correlate between Virana silethumam and Acute Pharyngo-tonsillitis.

MATERIALS AND METHODS

STUDY DESIGN & CONDUCT OF STUDY:

Study Type: An open clinical trial

Study Place: OPD & IPD of Ayothidass pandithar hospital,
National Institute of Siddha , Tambaram sanatorium, Chennai-47.

Study Period: 12 months

Population and Sample:

- The population consists of patients attending the OPD & IPD of Ayothidoss Pandithar Hospital, National Institute of Siddha, Chennai-47.
- The sample consists of 3 -12 years age group fulfilling the inclusion criteria.

Sample size: 40 patients

SUBJECT SELECTION:

As and when patients reporting with symptoms of inclusion criteria will be subjected to screening test & documented using screening Proforma.

INCLUSION CRITERIA:

1. Age : 3-12 Years
2. Sex : Both male & female children
3. Children with symptoms of cough, sore throat, fever with malaise, swollen tonsils, odynophagia and headache.
4. Patients whose parents/guardian are willing to sign the informed consent.
5. Patients who are willing to attend OPD once in 7 days/admitted in IPD of Ayothidass Pandithar Hospital.
6. Patients who are willing to provide blood, urine for lab investigations.

EXCLUSION CRITERIA:

- Patient with known history of Primary Complex, Diphtheria/whooping Cough, Allergic Rhinitis with Post nasal drip.
- H/O Congenital heart disease, seizure disorders.
- Other serious illnesses based on Parental information and previous reports.

WITHDRAWAL CRITERIA:

- Occurrence of serious adverse effects which may/may not be related to trial drug.
- Poor patient compliance.
- Patient turned unwilling to continue in the course of clinical trial.
- Exacerbation of symptoms

Name of the Trial Drug: Malli Chooranam**STANDARD OPERATING PROCEDURE:****INGREDIENTS:**

1. Parangi chakkai (smilax china) – 35gms
2. Athimathuram (Glycyrrhiza glabra) – 35gms
3. Karunseeragam (Nigella sativa) – 35gms
4. Seeragam (Cuminum cyminum) – 35gms
5. Pilapu seeragam Shah-zirah (Carum bulbocastum)– 35gms
6. Elam (Elettaria cardomomum) – 35gms
7. Sannalavanga pattai (Cinnamomum verum) – 35gms
8. Kirambu (Syzygium aromaticum)- 35gms
9. Viraiilla thiraichai (Vitis vinifera) – 35gms
10. Thania (Coriandrum sativum) – 315gms

I) SOURCE OF TRIAL MEDICINE:

The ingredients for preparation of experimental formulation **MALLI CHOORANAM** would be purchased from a well reputed country shop and raw drugs are authenticated by the help of Dept HOD and Herbal botanist and with Department of Gunapadam. The medicine will be prepared in Gunapadam lab of National institute of Siddha after proper purification. The prepared medicine also authenticated by the concerned Head Of The Dept for its completeness.

II) METHOD OF PURIFICATION & PREPARATION:

Malli Chooranam

Ref: Chikicha ratna deepam ,Pg.no. 120

PURIFICATION METHODS:

Parangisakkai: Initially the drug is dried & made into fine powder. Then milk is taken in a earthen ware vessel & its mouth is covered with cloth. Then the powder is kept on the cloth & it is covered with another earthen ware vessel. It is then boiled for 3 hours. The resultant powder is dried in sunlight & grinded.

Athimathuram: Wash with clean water & peel the outer layer. Then cut into small pieces and dry in sunlight.

Karunjseeragam: Remove the dust & dry it in sunlight. Then fry to golden brown colour.

Seeregam: Remove the dust & dry in sunlight.

Pilappu seeragam: Dried in sunlight.

Cardamom: Dried in sunlight.

Lavangapattai : Dried in sunlight

Kirambu : Dried in sunlight.

Thiratchai: Remove the dust.

Kothamalli: Tie it in a cloth, and boil in hot water or lime juice. Then dry in sunlight.

Method of preparation:

All the raw drugs given above except coriander seed are fried until to golden brown colour. Then the drugs are ground into a fine powder. It is filtered by using a fine cloth (Vasthirakaayam). Now equal amount of sweet candy powder is added with the chooranam and stored in air tight container.

DOSE : Arai thola (6gms)

- 1.5 grams for 3 to 7 years of age, twice daily
- 2.5 grams for 8 to 12 years of age, twice daily

(subjected to the verification of the therapeutic dose in animal models by toxicity studies)

ADJUVANT: Milk

DRUG DURATION: 7 days

INDICATIONS: Thondaipun, , Thondaikammal, Vikkal, Vaanthi, Kaatthadaippu

Arosikam, Athika viyarvai viduthal, Kaikaal erichal.

III)DRUG STORAGE:

The trial drug **Malli Chooranam** is stored in clean and dry wide mouthed glass bottle.

IV)DISPENSING:

The Malli chooranam is given in powder form as separate pockets of individual dose in a ziplock cover.

ASSESSMENTS & TEST :

- **CLINICAL ASSESSMENT**
- **ROUTINE INVESTIGATION**
- **SPECIFIC INVESTIGATION**
- **SIDDHA ASSESSMENT**

CLINICAL ASSESSMENT:

SYMPTOMS:

1. Cough
2. Fever, malaise and rigor
3. Sore throat with mucous and pustular exudates
4. Odynophagia
5. Headache
6. Swollen tonsils
7. Swelling of anterior and posterior cervical area lymph nodes
8. Burning sensation all over the body
9. Crying out of severity of disease.

ROUTINE INVESTIGATIONS:

BLOOD INVESTIGATIONS:

1. Haemoglobin
2. Total WBC Count
3. Differential Count
4. Total RBC count.
5. Erythrocyte Sedimentation Rate

URINE EXAMINATION:

1. Albumin
2. Deposits

SPECIFIC INVESTIGATION:

1. ASO Titre
2. CRP
3. Throat swab(if required)

SIDDHA ASSESSMENT:

1. Nilam
2. Kaalam
3. Uyirthathukal
4. Udalthathukal
5. Envagai thervu
6. Neerkuri
7. Neikuri

METHODOLOGY:

STUDY ENROLLMENT:

In the Phase II study, patients reporting at the OPD with the clinical symptoms of sore throat, odynophagia, headache, swollen tonsils, fever will be examined clinically for enrolling in the study based on the inclusion and exclusion criteria.

The patients who are to be enrolled would be informed about the study, trial drug, possible outcomes and the objectives of the study in the language and terms understandable to them.

After ascertaining the patients' willingness, informed consent (Form II) would be obtained in writing from their parents in the consent form.

All these patients will be given unique registration card in which patients' Registration number of the study, Address, Phone number and Doctors phone number etc. will be given, so as to report easily should any complications arise.

Complete clinical history, complaints and duration, examination findings-- all would be recorded in the prescribed Proforma in the history and clinical assessment forms separately. Screening Form- I will be filled up. Form III, Form –IV and Form –V will be used for recording the patients' history, clinical examination of symptoms and signs and laboratory investigations respectively.

Patient will be advised to take the trial drug and appropriate dietary advice would be given according to the patients' perfect understanding

CONDUCT OF THE STUDY:

The trial drug "MALLI CHOORANAM" will be given continuously for 7 days. On the 8th day patient will be requested to attend the OPD for clinical assessment and it will be recorded in the clinical assessment form and prognosis noted ..The patient's informant are requested to bring back the un-consumed trial drug if any. For IP patients the drug will be provided daily and prognosis noted. Laboratory investigations will be

done on 0 day & 15th day of the trial are recorded. After the completion of the treatment, the patient is advised to visit the OPD for another 1 months for follow-up. If any trial patient who fails to collect the trial drug on the prescribed day but wants to continue in the trial from the next day or two, he/ she will be allowed, but defaulters of one week and more will not be allowed to continue and be withdrawn from the study with fresh case being inducted.

DATA MANAGEMENT:

- After enrolling the patient in the study, a separate file for each patient will be opened and all forms will be filed in the file. Study No. and Patient No. will be entered on the top of file for easy identification. Whenever study patient visits OPD during the study period, the respective patient file will be taken and necessary recordings will be made at the assessment form or other suitable form.
- The screening forms will be filed separately.
- The Data recordings in all forms will be monitored and scrutinized by HOD, Dept of kuzhanthai maruthuvam .
- Data analysis will be done with the help of Senior Research Officer (statistics) of NIS.

OUTCOME :

PRIMARY OUTCOME:

Will be assessed by scoring in reduction of clinical symptoms before and after treatment.

SECONDARY OUTCOME:

Assessed by

1. Reduction of ESR
2. Reversal of Neutrophil leucocytosis.

ADVERSE EFFECT/SERIOUS EFFECT MANAGEMENT: If the trial patient develops any adverse reaction, he/she would be immediately withdrawn from the trial and proper management will be given in OPD of National Institute of Siddha and the same will be reported to regional pharmacovigilance centre.

ETHICAL ISSUES:

1. To prevent any infection, while collecting blood sample from the patient, only disposable syringes, disposable gloves, with proper sterilization of lab equipments will be used.
2. No other external or internal medicines will be used. There will be no infringement on the rights of patient.
3. The data collected from the patient will be kept confidentially.
4. The patient will be informed about the diagnosis, treatment and follow-up.
5. Informed consent will be obtained from the guardian of the patient after explaining in the understandable language to the patient and guardian.
6. After the consent from concerned guardian of the patient (through consent form) they will be enrolled in the study.
7. Treatment would be provided free of cost.
8. In conditions of treatment failure, adverse reactions, patients will be given alternative treatment at the National Institute of Siddha with full care throughout the end.
9. The patients with exclusion criteria not included in the trial will be treated as regular cases in the OPD of Ayothidass Pandithar Hospital.

ASSESSMENT FORMS

FORM I - SCREENING & SELECTION PROFORMA

FORM II - CONSENT FORM

FORM III - HISTORY PROFORMA

FORM IV - CLINICAL ASSESSMENT FORM

FORM V -LABORATORY INVESTIGATION FORM

FORM VI -PATIENT'S INFORMATION SHEET

FORM VII - WITHDRAWAL FORM

FORM VIII - ADVERSE REACTION FORM

FORM IX - DIETARY ADVICE FORM

ANNEXURE-II PROFORMA

NATIONAL INSTITUTE OF SIDDHA, CHENNAI-47.
AYOTHIDOSS PANDITHAR HOSPITAL
DEPARTMENT OF KUZHANDHAI MARUTHUVAM

A STUDY ON VIRANA SILETHUMAM (ACUTE PHARYNGO-TONSILLITIS) IN CHILDREN

FORM I - SCREENING FORM

1. SI NO: _____ 2 OP /IP NO: _____ 3. NAME: _____ 4. RELIGION: H / C / M / O
5. AGE: _____ 6. GENDER: M ☐ F ☐ 7. FATHER'S OCCUPATION: _____
8. INCOME: _____ 9. INFORMANT: _____ 10. RELIABILITY: _____

INCLUSION CRITERIA:

	YES	NO
1. COUGH	<input type="checkbox"/>	<input type="checkbox"/>
2. FEVER	<input type="checkbox"/>	<input type="checkbox"/>
3. MALAISE	<input type="checkbox"/>	<input type="checkbox"/>
4. SORE THROAT	<input type="checkbox"/>	<input type="checkbox"/>
5. DIFFICULTY TO SWALLOW	<input type="checkbox"/>	<input type="checkbox"/>
6. HEADACHE	<input type="checkbox"/>	<input type="checkbox"/>
7. SWOLLEN TONSILS	<input type="checkbox"/>	<input type="checkbox"/>
8. LAB INVESTIGATIONS-WILLING	<input type="checkbox"/>	<input type="checkbox"/>

EXCLUSION CRITERIA:

1. PRIMARY COMPLEX	<input type="checkbox"/>	<input type="checkbox"/>
2. DIPHTHERIA	<input type="checkbox"/>	<input type="checkbox"/>
3. CONGENITAL HEART DISEASES	<input type="checkbox"/>	<input type="checkbox"/>
4. ALLERGIC RHINITIS WITH POST NASAL DRIP	<input type="checkbox"/>	<input type="checkbox"/>
5. OTHER SERIOUS ILLNESSES	<input type="checkbox"/>	<input type="checkbox"/>

ADMITTED TO TRIAL:	<input type="checkbox"/>	<input type="checkbox"/>
IF YES, SERIAL NUMBER:	<input type="checkbox"/> <input type="checkbox"/>	

SIGNATURE OF INVESTIGATOR:
SIGNATURE OF LECTURER:
DATE:

NATIONAL INSTITUTE OF SIDDHA, CHENNAI-47.
AYOTHIDOSS PANDITHAR HOSPITAL
DEPARTMENT OF KUZHANDHAI MARUTHUVAM

A STUDY ON **VIRANA SILETHUMAM** (ACUTE PHARYNGO-TONSILLITIS)
IN CHILDREN

FORM II - CONSENT FORM

CERTIFICATE BY INVESTIGATOR

I certify that I have disclosed all details about the study in the terms readily understood by the parent.

Date:

Signature:

Name:

CONSENT OF THE INFORMANT:

I have been informed to my satisfaction, by the attending physician, the purpose of the clinical trial, and the nature of the drug treatment and follow-up including the laboratory investigations to be performed to monitor and safeguard my son/daughter body functions.

I am aware of my right to opt out of the trial to my son/daughter at any time during the course of the trial without having to give the reasons for doing so.

I, am exercising my free power of choice, hereby give my consent to include my son/daughter as a subject in the clinical trial of “**Malli chooranam**” in the treatment of ‘**Virana Silethumam (Acute Phayngo-tonsillitis)**’.

Date:

Station:

Name of the patient:

Signature of Parent/guardian:

Name:

Signature of Witness:

Name

நிறுவனத்தின் பெயர் : தேசிய சித்த மருத்துவ நிறுவனம்
அயோத்திதாசர் பண்டிதர் மருத்துவமனை,
சென்னை-47.

ஒப்புதல் படிவம்.

ஆய்வாளரால் சான்றளிக்கப்பட்டது.

நான் இந்த ஆய்வை குறித்த அனைத்து விபரங்களையும் நோயாளியின் பெற்றோர்/பாதுகாவலருக்கு புரியும் வகையில் எடுத்துரைத்தேன் என உறுதியளிக்கிறேன்.

தேதி:
இடம்:

கையொப்பம்:
பெயர்:

நோயாளியின் பெற்றோர்/பாதுகாவலரின் ஒப்புதல்:

என்னிடம் இந்த மருத்துவ ஆய்வின் காரணத்தையும், மருத்துவ வழிமுறை, மருந்தின் தன்மை மற்றும் தொடர்ந்து எனது குழந்தையின் உடல் இயக்கத்தை கண்காணிக்கவும், அதனை பாதுகாக்கவும் பயன்படும் மருத்துவ ஆய்வுகூட பரிசோதனைகள் பற்றியும் திருப்தி அளிக்கும் வகையில் ஆய்வு மருத்துவரால் விளக்கிக் கூறப்பட்டது.

நான் இந்த மருத்துவ ஆய்வின் போது காரணம் எதுவும் கூறாமல், எப்போது வேண்டுமானாலும் இந்த ஆய்வை விட்டு என் குழந்தையை விடுவித்து கொள்ளும் உரிமையை தெரிந்திருக்கிறேன்.

நான் என்னுடைய சுதந்திரமாக தேர்வு செய்யும் உரிமையைக் கொண்டு விரண சிலேத்தும நோய்க்கு மல்லி சூரணத்தின் பரிகரிப்புத் திறனைக் கண்டறியும் ஆய்விற்கு எனது குழந்தையை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி:
இடம்:

நோயாளியின் பெயர்:
பெற்றோர்/பாதுகாவலரின் கையொப்பம்:
பெயர்:
சாட்சியின் கையொப்பம்:
பெயர்:

NATIONAL INSTITUTE OF SIDDHA, CHENNAI-47.
AYOTHIDOSS PANDITHAR HOSPITAL
DEPARTMENT OF KUZHANDHAI MARUTHUVAM
**A STUDY ON VIRANA SILETHUMAM (ACUTE PHARYNGO-TONSILLITIS)
IN CHILDREN**
FORM III - PROFORMA

1. SI NO: _____ 2 OP /IP NO: _____ 3. NAME: _____ 4. RELIGION: H / C / M / O
5. AGE: _____ 6.GENDER: M ☐ F ☐ 7. FATHER'S OCCUPATION: _____
8. INCOME: _____ 9. POSTAL ADDRESS: _____

10. INFORMANT: _____ 11.CONTACT NUMBER: _____.

12. COMPLAINTS AND DURATION:

13. HISTORY OF PRESENT ILLNESS:

14. HISTORY OF PAST ILLNESS: YES NO

A.JAUNDICE:	<input type="checkbox"/>	<input type="checkbox"/>
B.SEIZURES:	<input type="checkbox"/>	<input type="checkbox"/>
C. PRIMARY COMPLEX	<input type="checkbox"/>	<input type="checkbox"/>
D.CHRONIC PULMONARY DISORDER	<input type="checkbox"/>	<input type="checkbox"/>
E. DEVELOPMENTAL DELAY	<input type="checkbox"/>	<input type="checkbox"/>
F.OTHERS (PLS SPECIFY) _____		

15. FAMILY HISTORY: ☐ ☐

16. PROPER IMMUNIZATION HISTORY: ☐ ☐

17. GENERAL HABITS:

A.NAIL BITING	<input type="checkbox"/>	<input type="checkbox"/>
B.THUMB SUCKING	<input type="checkbox"/>	<input type="checkbox"/>
C.PICA	<input type="checkbox"/>	<input type="checkbox"/>
D.UNHYGIENIC FOOD INTAKE (ROADSIDE EATERIES)	<input type="checkbox"/>	<input type="checkbox"/>
E.POOR PERSONAL HYGIENE	<input type="checkbox"/>	<input type="checkbox"/>
F.NOCTURNAL ENEURESIS	<input type="checkbox"/>	<input type="checkbox"/>

NORMAL

AFFECTED

G. APPETITE	<input type="checkbox"/>	<input type="checkbox"/>	
H.TYPE OF FOOD GIVEN:	<input type="checkbox"/> VEG	<input type="checkbox"/> NVEG	<input type="checkbox"/> MIXED _____
I. BOWELS:	<input type="checkbox"/>		<input type="checkbox"/> _____
J. MICTURITION:	<input type="checkbox"/>		<input type="checkbox"/> _____
K. SLEEP	<input type="checkbox"/>		<input type="checkbox"/> _____

18.GENERAL EXAMINATION:

A.HEIGHT (IN Cms) _____
B.WEIGHT (IN Kgs) _____
C.BMI: _____
D.TEMPERATURE (F) _____
E. HEART RATE _____/Min
F.PULSE RATE _____/Min
G.RESPIRATORY RATE _____/Min
H. BLOOD PRESSURE _____mm/Hg

	YES	NO
I. PALLOR	<input type="checkbox"/>	<input type="checkbox"/>
J. ICTERUS	<input type="checkbox"/>	<input type="checkbox"/>
K. CYANOSIS	<input type="checkbox"/>	<input type="checkbox"/>
L. CLUBBING	<input type="checkbox"/>	<input type="checkbox"/>
M. LYMPHADENOPATHY	<input type="checkbox"/>	<input type="checkbox"/>
N. PEDAL EDEMA	<input type="checkbox"/>	<input type="checkbox"/>
O. JUGULAR VENOUS PULSATIONS	<input type="checkbox"/>	<input type="checkbox"/>
P. CONGENITAL ABNORMALITIES	<input type="checkbox"/>	<input type="checkbox"/>

19.CLINICAL ASSESSMENT:

A.COUGH	<input type="checkbox"/>	<input type="checkbox"/> If yes _____
B.FEVER	<input type="checkbox"/>	<input type="checkbox"/> If yes _____
C.MALAISE	<input type="checkbox"/>	<input type="checkbox"/>
D.SORE THROAT	<input type="checkbox"/>	<input type="checkbox"/>
E.DIFFICULTY TO SWALLOW	<input type="checkbox"/>	<input type="checkbox"/>
F.HEADACHE	<input type="checkbox"/>	<input type="checkbox"/>
G. ANTERIOR CERVICAL LYMPHADENITIS	<input type="checkbox"/>	<input type="checkbox"/>
H.DIFFUSE MUCOSAL CONGESTION	<input type="checkbox"/>	<input type="checkbox"/>
I. INFLAMMATORY EXUDATES	<input type="checkbox"/>	<input type="checkbox"/>
J. PETECHIAE	<input type="checkbox"/>	<input type="checkbox"/>
K. PUSTULES	<input type="checkbox"/>	<input type="checkbox"/>
L.TONSILLAR HYPERTROPHY	<input type="checkbox"/>	<input type="checkbox"/> _____
M.OTHERS _____	<input type="checkbox"/>	<input type="checkbox"/>

20. EXAMINATION OF RESPIRATORY SYSTEM:

INSPECTION: _____

PALPATION: _____

PERCUSSION: _____

AUSCULTATION: _____

21. EXAMINATION OF OTHER SYSTEMS:

A.CARDIOVASCULAR SYSTEM: _____

B. ABDOMEN _____

C. CENTRAL NERVOUS SYSTEM _____

22. OTHER ASSESSMENTS :**A.NILAM:**KURINJI ☐ MULLAI ☐ MARUTHAM ☐ NEITHAL ☐ PAALAI ☐**B.KAALAM:**KAAR ☐ KOOTHIR ☐ MUNPANI ☐ PINPANI ☐ ILAVENIR ☐ MUDUVENIR ☐**C.YAKKAI:**

VALI ☐ AZHAL ☐ IYAM ☐
 VALI AZHAL ☐ VALI IYAM ☐ AZHAL VALI ☐
 AZHAL IYAM ☐ IYA VALI ☐ IYA AZHAL ☐

D. GUNAM:SATHUVAM ☐ RASATHAM ☐ THAMASAM ☐

	NORMAL	AFFECTED		NORMAL	AFFECTED
--	--------	----------	--	--------	----------

E.PORI:

MEI	<input type="checkbox"/>	<input type="checkbox"/>
VAAI	<input type="checkbox"/>	<input type="checkbox"/>
KANN	<input type="checkbox"/>	<input type="checkbox"/>
MOOKU	<input type="checkbox"/>	<input type="checkbox"/>
SEVI	<input type="checkbox"/>	<input type="checkbox"/>

PULAN:

UNARVU	<input type="checkbox"/>	<input type="checkbox"/>
SUVAI	<input type="checkbox"/>	<input type="checkbox"/>
PAARVAI	<input type="checkbox"/>	<input type="checkbox"/>
MOPPAM	<input type="checkbox"/>	<input type="checkbox"/>
KETTAL	<input type="checkbox"/>	<input type="checkbox"/>

F.KANMENDRIYAM:

KAI	<input type="checkbox"/>	<input type="checkbox"/>
KAAL	<input type="checkbox"/>	<input type="checkbox"/>
VAAI	<input type="checkbox"/>	<input type="checkbox"/>
ERUVAAI	<input type="checkbox"/>	<input type="checkbox"/>
KARUVAAI	<input type="checkbox"/>	<input type="checkbox"/>

KANMAVIDAYAM:

THAANAM	<input type="checkbox"/>	<input type="checkbox"/>
KAMANAM	<input type="checkbox"/>	<input type="checkbox"/>
VASANAM	<input type="checkbox"/>	<input type="checkbox"/>
VISARKAM	<input type="checkbox"/>	<input type="checkbox"/>
ANANDAM	<input type="checkbox"/>	<input type="checkbox"/>

G.UYIR THATHUKKAL**NORMAL****AFFECTED****1.VATHAM:**

PRANAN

☐☐

ABANAN

☐☐

UTHANAN

☐☐

VIYANAN

☐☐

SAMANAN

☐☐

NAGAN

☐☐

KOORMAN

☐☐

KIRUKARAN

☐☐

DEVADHATHAN

☐☐

DHANANJEYAN

☐☐**2.PITHAM:**

ANALAM

☐☐

RENJAGAM

☐☐

SATHAGAM

☐☐

PRASAGAM

☐☐

ALOSAGAM

☐☐**3.KAPHAM:**

AVALAMBAGAM

☐☐

KILETHAM

☐☐

POTHAGAM

☐☐

THARPAGAM

☐☐

SANTHIGAM

☐☐**H.UDAR THATHUKKAL**

SARAM

☐☐

SENNEER

☐☐

OON

☐☐

KOZHUPPU

☐☐

ENBU

☐☐

MOOLAI

☐☐

SUKKILAM/

☐☐

SURONITHAM

I.ENVAGAI THERVUGAL

	NORMAL	AFFECTED
1.NAA:		
NIRAM:	<input type="checkbox"/>	<input type="checkbox"/> _____
THANMAI:	<input type="checkbox"/>	<input type="checkbox"/> _____
SUVAI:	<input type="checkbox"/>	<input type="checkbox"/> _____
2.NIRAM:	<input type="checkbox"/>	<input type="checkbox"/> _____
3.MOZHI:	<input type="checkbox"/>	<input type="checkbox"/> _____
4.VIZHI:		
NIRAM:	<input type="checkbox"/>	<input type="checkbox"/> _____
THANMAI:	<input type="checkbox"/>	<input type="checkbox"/> _____
PAARVAI:	<input type="checkbox"/>	<input type="checkbox"/> _____
5. SPARISAM:	<input type="checkbox"/> VEPPAM	<input type="checkbox"/> MIDHA VEPPAM
	<input type="checkbox"/> OTHERS _____	<input type="checkbox"/> THATPAM

	NORMAL	AFFECTED
6. MALAM:		
NIRAM	<input type="checkbox"/>	<input type="checkbox"/> _____
NURAI	<input type="checkbox"/>	<input type="checkbox"/> _____
IRUGAL / ILAGAL	<input type="checkbox"/>	<input type="checkbox"/> _____
EDAI	<input type="checkbox"/>	<input type="checkbox"/> _____
7. MOOTHIRAM:		
NEERKURI:		
NIRAM:	<input type="checkbox"/>	<input type="checkbox"/> _____
NURAI:	<input type="checkbox"/>	<input type="checkbox"/> _____
MANAM:	<input type="checkbox"/>	<input type="checkbox"/> _____
ENJAL:	<input type="checkbox"/>	<input type="checkbox"/> _____
EDAI:	<input type="checkbox"/>	<input type="checkbox"/> _____
NEIKURI:		
SERPENTINE FASHION	<input type="checkbox"/>	
ANNULAR/RINGED FASHION	<input type="checkbox"/>	
PEARL BEADED FASHION	<input type="checkbox"/>	
MIXED FASHION	<input type="checkbox"/>	

1. NAADI:

THANI NADI: VALI ☐ AZHAL ☐ IYAM ☐

THONTHANADI: VALI AZHAL ☐ AZHAL VALI ☐ AZHAL IYAM ☐
IYA AZHAL ☐

MUKKUTRANADI ☐

THODANADI : VALI IYAM ☐ IYA VALI ☐

SIGNATURE OF INVESTIGATOR:

SIGNATURE OF LECTURER:

DATE:

NATIONAL INSTITUTE OF SIDDHA, CHENNAI-47.
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 DEPARTMENT OF KUZHANDHAI MARUTHUVAM
A STUDY ON VIRANA SILETHUMAM (ACUTE PHARYNGO-TONSILLITIS)
IN CHILDREN
FORM V - LAB PARAMETERS CHART

1. SI NO:____ 2 OP /IP NO:_____ 3. NAME: _____ 4 . AGE: ____5.GENDER: M ☐ F ☐

ROUTINE BLOOD INVESTIGATIONS		NORMAL VALUES	BEFORE TMT	AFTER TMT
Hb (gms%)		11.5 – 14.5		
T.RBC (milli /cu.mm)		4-4.9		
ESR (mm)	½ hr.	-		
	1 hr.	0-13		
T.WBC (milli /cu.mm)		5000-14500		
DIFFERENTIAL COUNT (%)	Polymorphs	40-75		
	Lymphocytes	28-48		
	Monocytes	3-6		
	Eosinophils	0-3		
	Basophils	0-1		
ASO				
CRP				

URINE INVESTIGATION	Before TMT	After TMT
Albumin		
Deposits		

DATE:

SIGNATURE OF INVESTIGATOR:

SIGNATURE OF LECTURER:

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**A STUDY ON VIRANA SILETHUMAM (ACUTE PHARYNGO-TONSILLITIS)
IN CHILDREN**

FORM IV - CLINICAL ASSESSMENT FORM

1. SI NO:____ 2 OP /IP NO:_____ 3. NAME: _____ 4 . AGE: ____ 5.GENDER: M ☐ F ☐

6. DATE OF ADMISSION TO THE TRIAL: ☐☐ ☐☐ ☐☐☐☐

7. CLINICAL ASSESSMENT:

	1 st day	8 th day	14 th day
TEMPERATURE(°F)			
PULSE RATE (per min)			
HEART RATE (per min)			
RESPIRATORYRATE (per min)			
COUGH			
FEVER			
MALAISE			
SORE THROAT			
DIFFICULTY TO SWALLOW			
HEADACHE			
ANT CERVICAL LYMPHADENITIS			
DIFFUSE MUCOSAL CONGESTION ***			
INFLAMMATORY EXUDATES			
PETECHIAE			
PUSTULES			
TONSILLAR HYPERTROPHY			

*** Of palate, faucial pillars, tonsil, posterior pharyngeal wall.

SIGNATURE OF INVESTIGATOR:

SIGNATURE OF LECTURER:

NATIONAL INSTITUTE OF SIDDHA, CHENNAI-47.
AYOTHIDOSS PANDITHAR HOSPITAL
DEPARTMENT OF KUZHANDHAI MARUTHUVAM
**A STUDY ON VIRANA SILETHUMAM (ACUTE PHARYNGO-TONSILLITIS)
IN CHILDREN
FORM VII - WITHDRAWAL FORM**

1. SI NO: ____ 2 OP /IP NO: _____ 3. NAME: _____ 4. AGE: __ 5.GENDER: M ☐ F ☐

6. POSTAL ADDRESS: _____

7. DATE OF ADMISSION TO TRIAL:

8. DATE OF WITHDRAWAL FROM TRIAL:

9. REASONS FOR WITHDRAWAL:

- LONG ABSENCE AT REPORTING ☐
- IRRREGULAR TREATMENT ☐
- SHIFT OF LOCALITY ☐
- INCREASE IN SEVERITY OF SYMPTOMS ☐
- DEVELOPMENT OF ADVERSE DRUG REACTIONS ☐
- ANY OTHER _____

10.CURRENT STATUS OF THE PATIENT:

DATE:

SIGNATURE OF INVESTIGATOR:

SIGNATURE OF LECTURER:

NATIONAL INSTITUTE OF SIDDHA, CHENNAI-47.
AYOTHIDOSS PANDITHAR HOSPITAL
DEPARTMENT OF KUZHANDHAI MARUTHUVAM

**A STUDY ON VIRANA SILETHUMAM (ACUTE PHARYNGO-TONSILLITIS)
IN CHILDREN
FORM IX- DRUG COMPLIANCE FORM**

1. SI NO: ____ 2 OP /IP NO: _____ 3. NAME: _____ 4 . AGE: ____ 5.GENDER: M ☐ F ☐

NAME OF THE DRUG: MALLI CHOORANAM.

FORM OF THE DRUG: POWDER

ADMINISTRATION & ADJUVANT: PER ORAL, IN MILK

DOSE & DURATION: 1.5-2.5gms, TWICE DAILY FOR 7 DAYS

NO. OF DRUG PACKETS GIVEN: ☐☐

NO. OF DRUG PACKETS RETURNED: ☐☐

DAY	DATE OF DRUG INTAKE	MORNING	EVENING
DAY 1			
DAY2			
DAY 3			
DAY 4			
DAY 5			
DAY 6			
DAY 7			

SIGNATURE OF INVESTIGATOR:

SIGNATURE OF LECTURER:

DATE:

NATIONAL INSTITUTE OF SIDDHA, CHENNAI-47.
AYOTHIDOSS PANDITHAR HOSPITAL
DEPARTMENT OF KUZHANDHAI MARUTHUVAM

**A STUDY ON VIRANA SILETHUMAM (ACUTE PHARYNGO-TONSILLITIS)
IN CHILDREN
FORM VIII - ADVERSE REACTION (PHARMACO-VIGILANCE) FORM**

1. SI NO: ____ 2 OP /IP NO: _____ 3. NAME: _____ 4. AGE: ____ 5.GENDER M ☐ F ☐

6.Date of trial commencement:

7.Date of occurrence of adverse reaction :

8.Description of adverse reaction:

SIGNATURE OF INVESTIGATOR:

SIGNATURE OF LECTURER:

DATE:

விரண சிலேத்துமம் என்னும் தொண்டை நோய்க்கான சித்த மருந்து மல்லி
சூரணம் பரிகரிப்புத்திறனைக் கண்டரியும் மருத்துவ ஆய்விற்கான

தகவல் படிவம்:

முதன்மை ஆராய்ச்சியாளர்: மரு.அ.ரேணுகா
நிறுவனத்தின் பெயர்: தேசிய சித்த மருத்துவ நிறுவனம்,
சென்னை-47

ஒரு வருட காலம் மேற்கொள்ளும் இந்த ஆய்வில் 40 நோயாளிகள்
தேர்ந்தெடுக்கப்பட்டு 7 நாட்கள் சிகிச்சைக்கு உட்படுத்தப்படுவார்கள். இம்மருந்து 3
முதல் 7 வயதுள்ள குழந்தைகளுக்கு 1.5கி மற்றும் 8 முதல் 12 வயதுள்ள
குழந்தைகளுக்கு 2.5கி தினம் இருவேளை அளவாக தரப்படும்.

இந்த மருத்துவ ஆய்விற்காக கட்டணம் எதுவும் வசூலிக்கப்படமாட்டாது.
இந்த ஆய்வின் மூலம் நோயாளிக்கு எவ்வித பாதிப்பும் ஏற்படாது. நோயாளியை
பற்றிய குறிப்புகள் ரகசியமாக பராமரிக்கப்படும்.

இந்த ஆய்வின் போது நோயாளிக்கு வேறு பாதிப்புகள் ஏற்படும் பட்சத்தில் தேசிய
சித்த மருத்துவமனையில் தக்க சிகிச்சை அளிக்கப்படும். இம்மருந்து விரண
சிலேத்துமம் என்னும் தொண்டை நோய்க்காக மூலிகை பொருட்களால்
தயாரிக்கப்படுவதாலும், தொடர்ந்து பயன்படுத்தப்பட்டு வருவதாலும் இம்மருந்தினால்
வேறு பாதிப்பு ஏற்படாது. இந்த ஆய்வில் நோயினராக சேர்ந்த பிறகும் விருப்பம்
இல்லையெனில் எப்போது வேண்டுமானாலும் விலகிக் கொள்ளலாம்.

அதற்கான இந்த ஆராய்ச்சி சம்பந்தமான மற்ற விபரங்களுக்கு முதன்மை
ஆராய்ச்சியாளரான மரு.அ.ரேணுகாவை 9894765816 என்ற எண்ணில் தொடர்பு
கொள்ளலாம்.

சிகிச்சா ரத்ன தீபத்தில் கூறப்பட்டுள்ள சூரணத்தில் மல்லி, கிராம்பு, ஏலம் முதலிய
கப நோய் நிவாரண பொருட்கள் சேர்க்கப்பட்டு தேசிய சித்த மருத்துவ
ஆய்வுகூடத்தில் நேர்த்தியாக முடிக்கப்பட்டது. தங்களது விருப்பத்தின் பேரில்
குழந்தையை ஆய்வுக்கு உட்படுத்தும் பட்சத்தில் இதனுடன் இணைக்கப்படும் ஒப்புதல்
படிவத்தில் தங்கள் கையெழுத்து பெறப்படும்.

INFORMATION SHEET regarding the clinical research of the therapeutic benefits of Siddha drug MALLI CHOORANAM in treating VIRANA SILETHUMAM.

Principal investigator: Dr.A.RENUGA

Place of study: National Institute of Siddha,
Chennai-47.

In this 1 year study, 40 patients are to be treated for 7 days. The drug would be dispensed to the patients in doses of 1.5gms (3-7years of age) and 2.5gms (in 8-12 years of age).

Through this study a safe, cost effective and reliable drug for throat infection can be made known to the world. There will be no risk of physical, psychological or professional means, by taking part in this study. Information of your son/daughter will be kept confidential.

In the event of development of any other illness, he/she will be treated in OPD/IPD of the hospital. The herbal medicine will not cause any risk to his/her life or health condition. You can wish not to take part or withdraw from the study at any time out of your own free will.

If you agree to make your son/daughter a participant in the study, blood (2ml) and urine investigations will be carried out on the before and after treatment to monitor health status. The medicine and investigations are free of cost.

If you wish to find out more about this study, you can contact Dr.A.RENUGA,,PG Scholar cum Principal Investigator of the study through mobile number 9894765816.

The drug MALLI CHOORANAM as stated in Chickicha ratna deepam, consists of coriander seeds, clove, elaichi and other ingredients with the property of healing throat infections.

Your son/daughter will be made a participant in this study, primarily after you sign the consent form on account of wishing to enroll him/her.

ANNEXURE-3

PREPARATION OF TRIAL MEDICINE

Malli Chooranam

INGREDIENTS:

1. Parangi chakkai (smilax china)
2. Athimathuram (Glycyrrhiza glabra)
3. Karunseeragam (Nigella sativa)
4. Seeragam (Cuminum cyminum)
5. Pilapu seeragam Shah-zirah (Carum bulbocastum)
6. Elam (Elettaria cardomomum)
7. Sannalavanga pattai (Cinnamomum verum)
8. Kirambu (Syzygium aromaticum)
9. Viraiilla thiraichai (Vitis vinifera)
10. Thania (Coriandrum sativum)

Ref: Chikicha ratna deepam ,Pg.no. 120

Method of preparation:

All the raw drugs given above except coriander seed are fried until to golden brown colour. Then the drugs are ground into a fine powder. It is filtered by using a fine cloth (Vasthirakaayam). Now equal amount of sweet candy powder is added with the chooranam and stored in air tight container.

DOSE : Arai thola (6gms)

- 1.5 grams for 3 to 7 years of age, twice daily
- 2.5 grams for 8 to 12 years of age, twice daily

ADJUVANT: Milk

DRUG DURATION: 7 days

INDICATIONS: Thondaipun, , Thondaikammal, Vikkal, Vaanthi, Kaatthadaippu

Arosikam, Athika viyarvai viduthal, Kaikaal erichal.



Coriandrum sativum



Elettaria cardamomum



Syzygium aromaticum



Cuminum cyminum



Cinnamomum verum



Carum bulbocastum



Nigella sativa



Glycyrrhiza glabra



Smilax china



Vitis vinifera



NATIONAL INSTITUTE OF SIDDHA

ACUTE TOXICITY STUDY OF MALLI CHOORANAM

[WHO guidelines, 1993]

Principle:

Acute toxicity was carried out in Swiss albino mice with a single exposure of 10 times of the recommended therapeutic dose of test compound the study duration will be 14 days.

Animal species	:	Swiss albino mice
Age / Weight / Size	:	6 weeks. Mice-20-25 gms.
Gender	:	Both male and female
Number of Animals	:	Mice: 10
Acclimatization Period	:	7 Days
Clinical dose	:	5.0 gms\day

S.No	Group	No of mice
1	Vehicle control (saline)	10 (5 male, 5 female)
2	Toxic dose 10X therapeutic dose (54mg)	10 (5 male, 5 female)

Test Animals

Test animals were obtained from the animal laboratory of the King institute, Chennai and stocked at National institute of siddha, Chennai. All the animals were kept under standard environmental condition (27+ or – 2 degree c).The animals had free access to water

and standard pellet diet (Sai Durga foods pvt.ltd, Bangalore).The principles of laboratory animal care were followed and the Institutional ethical committee approved the use of animals and the study design. (1248/ac/09/CPCSEA/February/ 2012)

Route of administration:

Oral route was selected, because it is the normal route of clinical administration.

Test substance and vehicle

Malli Chooranam is light greenish yellow in colour. The test substance is insoluble in water, in order to obtain and ensure the uniformity in drug distribution the drug is dissolved by aqueous Tween 80 solution (30%).

Administration of doses

Malli Chooranam was suspended in aqueous Tween 80 solution (30%), with uniform mixing and it was administered to the groups in a single oral dose .The control groups were received equal volume of the vehicle. The animals were weighed before giving the drug. The dose level was calculated according to body weight, and surface area. Since the clinical dose was 3.0gms\day it was converted to animal dose (54mg) and then administered. The principle of laboratory animal care was followed.

Observations

Observations were made and recorded systematically and continuously observed as per the guideline after substance administration. The animals were monitored for behavioural parameters like

1. Awareness

- Alertness
- Visual placing
- Stereotype
- Passivity
-

2. Mood

- Grooming

- Restlessness
- Irritability
- Fearfulness

3. Motor activity

- Spontaneous activity
- Reactivity
- Touch response
- Pain response.

Animals were observed for body weight and mortality for 14 days. If animals died during the period of study, the animals were sacrificed. At the end of the 14th day all animals were sacrificed and necropsy was done.

Body Weight

Individual weight of animals was determined before the test substance was administered and daily for 14 days. Weight changes were calculated and recorded. At the end of the test, surviving animals were weighed and sacrificed.

Results:

Malli Chooranam at the dose 54mg/animal did not exhibit any mortality in mice.

No behavior changes were noted for the first 4 hours and for the next 24 hours and throughout the study period of 14 days. No weight reduction was noted before and after the acute study duration. Reflexes were found to be normal before and after the study. All other observations were found to be normal before and after the study. In Necropsy, the organs of the animal such as, Liver, Heart, Lungs, Pancreas, Spleen, Stomach, Intestine, Kidney, Urinary bladder, Uterus all appeared normal.

ANNEXURE-5

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NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 600047

CERTIFICATE OF BOTANICAL AUTHENTICITY

Certified that the following plant drugs used in the Siddha formulation **Malli Chooranam** (Internal) for the treatment of **Virana Silethumam** (Acute Pharyngo tonsillitis) taken up for Post Graduation Dissertation studies by **Dr.A.Renuga**, M.D.(S), II year, Department of Kuzhandhai Maruthuvam, 2011-12, are identified and authenticated through Visual inspection / Experience, Education & Training/ Organoleptic characters/ Morphology / Micromorphology / Taxonomical/ Microscopical methods.

Smilax china Linn. (Liliaceae), Root

Glycyrrhiza glabra Linn. (Fabaceae), Root

Nigella sativa Linn. (Ranunculaceae), Seed

Cuminum cyminum Linn. (Apiaceae), Fruit

Carum bulbocastanum Koch. (Apiaceae), Fruit

Elettaria cardamomum Maton (Zingiberaceae), Fruit

Cinnamomum verum Presl. (Lauraceae), Stem Bark

Syzygium aromaticum (Linn.) Merr. & L.M. Perry (Myrtaceae), Flower bud

Vitis vinifera Linn. (Vitaceae), Dried fruit

Coriandrum sativum Linn. (Apiaceae), Fruit

Certificate No: NIS/MB/52/2012

Date: 12-3-12

Authorized Signatory

Dr. D. ARAVIND, M.D.(s), M.Sc.,

Assistant Professor

Department of Medicinal Botany

National Institute of Siddha

Chennai - 600 047, INDIA

IAEC - PROTOCOL - 1248/ac/09/CPCSEA/4-29/2011.

20/12/2011

CERTIFICATE

This is certify that the project title Preclinical & Clinical study on
Vizana Silethuvay (Acute Pharyngotonsillitis) in children and the
has been approved by the IAEC. Drug of choice is Malli chooranam.

Prof. Dr. K. Marickavarakam

Name of Chairman/Member Secretary IAEC:

Dr. B. Jayachandran Dare

Name of CPCSEA nominee:

Signature with date

K. Marickavarakam

Chairman/Member Secretary of IAEC:

B. Jayachandran Dare

CPCSEA nominee:

(Kindly make sure that minutes of the meeting duly signed by all the participants are maintained by Office)



NATIONAL INSTITUTE OF SIDDHA

(An Autonomous Body under Department of AYUSH)
Ministry Of Health & Family Welfare, Government of India

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Website : www.nischennai.org

Name: A. RENUKA, Reg. no. 32102705

Title: Preclinical & Clinical Study on Vitha Silethuvam (Acute Pharyngo-Tonsillitis) in children and the drug of choice is Halli Chooranare.

No. NIS/IEC/2011/3/29 - 24/12/2011

DECISION

Opinion of the Institutional Ethics Committee – Please Check one

☒ Approval

☐ Modifications required prior to approval (Please specify one space below)

☐ Disapproval

Date of review: _____

K. Manickavasagam
(Dr. K. MANICKAVASAGAM)
Member Secretary

Signed: L. Visuvanathan (Please print name) Dr. V. SUBRAMANIAN

Chair Person

(Please delete as appropriate, Chairperson, Secretary)

Modifications needed

Modification given to candidate

The research proponent is hereby informed that the Institutional Ethics Committee will require the following:

1. All adverse drug reactions (ADRs) that are both serious and unexpected to be reported promptly to the IEC within 7 working days
2. The progress report to be submitted to the IEC atleast annually
3. Upon completion of the study, a final study status report needs to be submitted to the IEC